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4 deps@golkow.com

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| <p style="text-align: right;">Page 214</p> <p>1 APPEARANCES:</p> <p>2</p> <p>3 MAZIE SLATER KATZ & FREEMAN, LLC</p> <p>4 BY: ADAM M. SLATER, ESQ.</p> <p>5 103 Eisenhower Parkway, 2nd Floor</p> <p>6 Roseland, NJ 07068</p> <p>7 973-228-9898</p> <p>8 aslater@mskf.net</p> <p>9 Counsel for Plaintiffs</p> <p>10</p> <p>11 BERNSTEIN LIEBHARD LLP</p> <p>12 BY: JEFFREY S. GRAND, ESQ.</p> <p>13 10 E. 40th Street, 22nd Floor</p> <p>14 New York, NY 10016</p> <p>15 212-779-1414</p> <p>16 grand@bernlieb.com</p> <p>17 Counsel for Plaintiffs</p> <p>18</p> <p>19 BUTLER, SNOW, O'MARA, STEVENS & CANNADA, PLLC</p> <p>20 BY: CHRISTY D. JONES, ESQ.</p> <p>21 1020 Highland Colony Parkway, Suite 1400</p> <p>22 Ridgeland, MS 39157</p> <p>23 601-948-5711</p> <p>24 christy.jones@butlersnow.com</p> <p>25 Counsel for Johnson & Johnson and Ethicon</p> <p>1</p> <p>2 BUTLER, SNOW, O'MARA, STEVENS & CANNADA, PLLC</p> <p>3 BY: NILS B. (BURT) SNELL, ESQ.</p> <p>4 500 Office Center Drive, Suite 400</p> <p>5 Fort Washington, PA 19034</p> <p>6 267-513-1884</p> <p>7 burt.snell@butlersnow.com</p> <p>8 Counsel for Johnson & Johnson and Ethicon</p> <p>9</p> <p>10 SILLS CUMMIS & GROSS, P.C.</p> <p>11 BY: WILLIAM R. STUART, ESQ.</p> <p>12 One Riverfront Plaza</p> <p>13 Newark, NJ 07102</p> <p>14 973-643-0700</p> <p>15 wstuart@sillscummis.com</p> <p>16 Counsel for Caldera Medical, Inc., and Synovis</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p> | <p style="text-align: right;">Page 216</p> <p>1 I N D E X</p> <p>2 WITNESS: Page</p> <p>3 ANNE M. WEBER, M.D., M.S.</p> <p>4 By Ms. Jones.....220, 380</p> <p>5 By Mr. Slater.....374, 381</p> <p>6</p> <p>7</p> <p>8</p> <p>9 E X H I B I T S</p> <p>10 (Attached.)</p> <p>11 No. Description Page</p> <p>12 1220 List entitled "Materials 322</p> <p>13 Reviewed"</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p> |
| <p style="text-align: right;">Page 215</p> <p>1 APPEARANCES VIA PHONE AND STREAM:</p> <p>2</p> <p>3 KLINE & SPECTER, P.C.</p> <p>4 BY: ROGER CAMERON, ESQ.</p> <p>5 1525 Locust Street, 19th Floor</p> <p>6 Philadelphia, PA 19102</p> <p>7 215-772-1000</p> <p>8 roger.cameron@KlineSpecter.com</p> <p>9 Counsel for Plaintiffs</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p> | <p style="text-align: right;">Page 217</p> <p>1 DEPOSITION SUPPORT INDEX</p> <p>2 - - -</p> <p>3</p> <p>4 Direction to Witness Not to Answer</p> <p>5 Page Line</p> <p>6 NONE</p> <p>7</p> <p>8 Request for Production of Documents</p> <p>9 Page Line</p> <p>10 285 8</p> <p>11</p> <p>12 Stipulation</p> <p>13 Page Line</p> <p>14 NONE</p> <p>15</p> <p>16 Question Marked</p> <p>17 Page Line</p> <p>18 NONE</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p> |

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| <p style="text-align: right;">Page 218</p> <p>1 CONFIDENTIAL DESIGNATION INDEX</p> <p style="text-align: center;">- - -</p> <p>2 PAGE 222 LINE 18 THROUGH PAGE 223 LINE 3</p> <p>3 PAGE 223 LINE 12 THROUGH PAGE 223 LINE 17</p> <p>4 PAGE 226 LINE 20 THROUGH PAGE 227 LINE 10</p> <p>4 PAGE 240 LINE 3 THROUGH PAGE 240 LINE 18</p> <p>5 PAGE 250 LINE 24 THROUGH PAGE 251 LINE 7</p> <p>6 PAGE 254 LINE 8 THROUGH PAGE 254 LINE 15</p> <p>7 PAGE 260 LINE 7 THROUGH PAGE 260 LINE 13</p> <p>8 PAGE 278 LINE 15 THROUGH PAGE 278 LINE 23</p> <p>9 PAGE 338 LINE 9 THROUGH PAGE 339 LINE 8</p> <p>10 PAGE 340 LINE 7 THROUGH PAGE 341 LINE 1</p> <p>11 PAGE 341 LINE 17 THROUGH PAGE 342 LINE 12</p> <p>12 PAGE 357 LINE 15 THROUGH PAGE 358 LINE 2</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p> | <p style="text-align: right;">Page 220</p> <p>1 ...ANNE M. WEBER, M.D., M.S., after</p> <p>2 having been duly sworn, was examined and</p> <p>3 testified as follows:</p> <p style="text-align: center;">- - -</p> <p>4 EXAMINATION</p> <p>5 BY MS. JONES:</p> <p>6 Q Doctor, as we mentioned yesterday and as</p> <p>7 you know, you have submitted in this litigation</p> <p>8 voluminous reports with your opinions that include</p> <p>9 what I'll call a general report and then</p> <p>10 case-specific reports for Ms. Gross and Ms. Wicker;</p> <p>11 correct?</p> <p>12 A Correct.</p> <p>13 Q And you have since supplemented with some</p> <p>14 additional reports after you have read or reviewed</p> <p>15 additional materials; am I correct?</p> <p>16 A Correct.</p> <p>17 Q And we were furnished last Friday or over</p> <p>18 the weekend with an updated list of materials that</p> <p>19 you had reviewed. And with the exception of</p> <p>20 Dr. Lucente's deposition, which was taken on Friday,</p> <p>21 I assume that that list is correct and complete to</p> <p>22 the best of your knowledge?</p> <p>23 A Yes.</p> <p>24 Q Are all of your opinions that you intend</p> <p>25</p> |
| <p style="text-align: right;">Page 219</p> <p>1 CONFIDENTIAL DESIGNATION INDEX</p> <p style="text-align: center;">- - -</p> <p>2</p> <p>3</p> <p>4</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p> | <p style="text-align: right;">Page 221</p> <p>1 to offer at the trial set forth in the reports that</p> <p>2 you have prepared?</p> <p>3 A Yes.</p> <p>4 Q Do you anticipate any additional work</p> <p>5 specifically with respect to Ms. Gross or</p> <p>6 Ms. Wicker?</p> <p>7 MR. SLATER: Objection.</p> <p>8 You can answer.</p> <p>9 THE WITNESS: I think that depends on</p> <p>10 what's produced between now and trial.</p> <p>11 BY MS. JONES:</p> <p>12 Q Let me clarify. I understand you may</p> <p>13 review some additional depositions or documents, but</p> <p>14 have you requested, for example, any materials on</p> <p>15 either of those patients that you wish to review</p> <p>16 that you've not yet had an opportunity to review?</p> <p>17 A No.</p> <p>18 Q Have you requested an opportunity to</p> <p>19 examine either of those women?</p> <p>20 A No.</p> <p>21 Q Have you requested an opportunity to visit</p> <p>22 with either of those women?</p> <p>23 A No.</p> <p>24 Q I take it that you are comfortable</p> <p>25 arriving at your opinions with respect to those</p> |

3 (Pages 218 to 221)

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| <p style="text-align: right;">Page 222</p> <p>1 women based upon the contents of the medical records 2 and the depositions that you've reviewed? 3 A And the reports. 4 Q And what reports? 5 A The reports from the people who have 6 examined them. 7 Q Those who have examined them specifically 8 for purposes of this litigation? 9 A Yes. 10 Q Do you have any criticisms of the treating 11 surgeons or doctors who implanted the Prolift®s in 12 either Ms. Gross or Ms. Wicker? 13 A No. 14 Q Do you believe and is it your opinion that 15 each of those women was an appropriate candidate for 16 the use of Prolift®? 17 A I do not agree. 18 Q Well, let me see if I can separate these 19 out. Is it your judgment that it is a breach of the 20 standard of care for a doctor to use Prolift® in any 21 woman? 22 A I wouldn't call it a breach of the 23 standard of care. I would call it a deception on 24 the part of Ethicon when they illegally marketed the 25 Prolift® and did not notify physicians and patients</p> | <p style="text-align: right;">Page 224</p> <p>1 misbranded in any way? 2 MR. SLATER: To her knowledge? 3 THE WITNESS: Not to my knowledge. 4 BY MS. JONES: 5 Q The FDA did clear Gynemesh® PS, did it 6 not? 7 A Yes, it did. 8 Q That was in 2002? 9 A Yes. 10 Q The mesh in Prolift® is identical to that 11 mesh? 12 A Yes. Excuse me. The mesh in Prolift® was 13 cut by a different method, it was not identical. 14 Q I'm sorry. It was not what? 15 A It was not identical. 16 Q It was in a different shape; correct? 17 A It was cut by a different method. 18 Q It was also in a different shape, was it 19 not? 20 A Correct, it was in a different shape. 21 Q And Gynemesh® PS was modified and cut by 22 surgeons in order to use it transvaginally, was it 23 not? 24 A Correct. 25 Q Mesh has been used and cut to be used in</p> |
| <p style="text-align: right;">Page 223</p> <p>1 that was the case. Physicians were assuming they 2 were using a properly FDA-cleared device and that 3 was untrue. 4 MS. JONES: Move to strike as 5 nonresponsive. 6 BY MS. JONES: 7 Q Doctor, in terms of whether or not the 8 device was legally marketed, are you aware of the 9 guidances that recognize that certain devices do not 10 require 510(k) clearance prior to marketing? 11 A I am aware. 12 Q Has the FDA ever begun, to your knowledge, 13 any type of enforcement proceedings against Ethicon 14 with respect to Prolift®? 15 A The FDA informed Ethicon that it could not 16 market Prolift® until the clearance process was 17 completed, and Ethicon did that anyway. 18 MS. JONES: Move to strike as 19 nonresponsive. 20 BY MS. JONES: 21 Q My question, Doctor, was: Has the FDA 22 ever initiated any enforcement proceedings against 23 Ethicon with respect to the marketing of Prolift®? 24 A No. 25 Q Has the FDA ever declared Prolift®</p> | <p style="text-align: right;">Page 225</p> <p>1 transvaginal surgeries since the 1990s, has it not? 2 MR. SLATER: You're talking mesh in 3 general; right? 4 MS. JONES: Uh-huh. 5 THE WITNESS: Correct. 6 BY MS. JONES: 7 Q And that mesh in general was cut and used 8 to be used transvaginally by surgeons without FDA 9 clearance for use in that manner; correct? 10 A That's an entirely different situation. 11 Off-label use by physicians is allowable. Illegal 12 marketing by a company is not. 13 MS. JONES: Let's just move to strike 14 as nonresponsive. 15 BY MS. JONES: 16 Q Can you answer my question, Doctor? 17 MS. JONES: Do you want to read back 18 my question. 19 MR. SLATER: She probably thinks she 20 did answer the question, as I do. 21 You understand when she moves to 22 strike, she's preserving her rights for the future. 23 It doesn't mean that your testimony is actually 24 going to be stricken because I'm obviously going to 25 oppose those motions. I just want you to know</p> |

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| <p style="text-align: right;">Page 226</p> <p>1 procedurally what she's doing. She's just 2 preserving her rights. It's perfectly fine to move 3 to strike. 4 THE WITNESS: Okay. Could you repeat 5 the question, please? 6 (The court reporter read the record 7 as follows: 8 "QUESTION: And that mesh in general 9 was cut and used to be used transvaginally by 10 surgeons without FDA clearance for use in that 11 manner; correct?") 12 THE WITNESS: Correct. I'd like to 13 expand on that. 14 MR. SLATER: You can. 15 THE WITNESS: The off-label use by 16 physicians of a material or a drug is allowable. 17 Illegal marketing of a commercial product without 18 FDA clearance is not. 19 BY MS. JONES: 20 Q Would you identify for me one place, 21 Doctor, just one place, where the FDA has ever 22 suggested that Ethicon illegally marketed Prolift®? 23 A In the letters -- in the process -- in the 24 interaction between FDA and Ethicon, the letter 25 stated you may not market this device while this</p> | <p style="text-align: right;">Page 228</p> <p>1 A Yes. 2 Q You use tools when you do abdominal 3 surgery, do you not? 4 A Yes. 5 Q You use tools when you do any type of 6 Prolift® surgery, don't you? 7 A Yes. 8 Q In terms of -- 9 A I'd like to expand on that, if I may. You 10 use tools that the hospital buys and the surgeon may 11 request that are also used for other procedures. 12 The tools in the Prolift® procedure were developed 13 for use for the Prolift® procedure and only the 14 Prolift® procedure. 15 Q Those tools were developed by surgeons, 16 weren't they? 17 A No. They were developed by Ethicon. 18 Q You don't think that they were developed 19 working with surgeons? 20 A They were developed working with surgeons. 21 Q And that surgeons use those tools? 22 MR. SLATER: Is that a question? 23 MS. JONES: That is a question. 24 THE WITNESS: They only use those 25 tools because Prolift® is made available as a kit.</p> |
| <p style="text-align: right;">Page 227</p> <p>1 process of clearance is ongoing. 2 Q Have you ever spoken with anyone at the 3 FDA about that? 4 A No. 5 Q Have you ever seen, Doctor, anywhere in 6 writing anyplace where the FDA said we consider that 7 Ethicon illegally marketed the device? 8 A FDA determined, when they finally realized 9 Prolift® was on the market, that it required a 10 separate application for clearance. 11 MS. JONES: Move to strike as 12 nonresponsive. 13 BY MS. JONES: 14 Q My question, Doctor, was: Have you ever 15 seen anyplace where the FDA said specifically we 16 consider that Prolift® was illegally marketed? 17 MR. SLATER: You mean where those 18 exact words were used? 19 MS. JONES: That's exactly what I'm 20 asking. 21 THE WITNESS: No. 22 BY MS. JONES: 23 Q When surgeons began using mesh for 24 transvaginal surgery in the 1990s, they used tools 25 to place that mesh, did they not?</p> | <p style="text-align: right;">Page 229</p> <p>1 BY MS. JONES: 2 Q Those tools were used by surgeons before 3 it was marketed as a kit, were they not? 4 A No. 5 Q Never? 6 A No. 7 Q That's your testimony? 8 A Yes, it is. 9 Q Have you ever used any of the Prolift® 10 tools? 11 A No. 12 Q Prior to being engaged in this litigation, 13 did you ever see any of those Prolift® tools? 14 A No. 15 Q If we go back to your testimony with 16 respect to Ms. Gross and Ms. Wicker, am I correct 17 that you testified that you have no criticisms of 18 the implanting surgeons? 19 A The surgeons followed the standard 20 procedure of Prolift® implantation. My criticism is 21 of the Prolift® procedure and mesh implantation. 22 Q My question, Doctor, was as follows: Do 23 you have any criticism whatsoever of the doctors who 24 chose to use Prolift® in Ms. Gross and Ms. Wicker? 25 A No, I do not.</p> |

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| <p style="text-align: right;">Page 230</p> <p>1 Q If we go back to the appropriate 2 treatments for prolapse, I think you identified 3 three different classes of treatment, if you will. 4 One is observational, just watching, if the patient 5 seems to be asymptomatic; correct? 6 A Technically observation is not a form of 7 treatment. 8 Q If a woman has prolapse but seems to be 9 asymptomatic, is it appropriate to observe and delay 10 any treatment? 11 A Yes. 12 Q Other therapies that are available would 13 be exercises, as we've discussed, correct -- 14 A Yes. 15 Q -- pelvic floor exercises? And the use of 16 pessaries; correct? 17 A Correct. And also behavioral and 18 lifestyle changes. 19 Q In terms of pessaries, the pessaries are 20 not suitable for treatment for every woman's 21 prolapse, are they? 22 A No, they are not. 23 Q And, indeed, pessaries may be difficult 24 for some women to use; is that right? 25 A That is correct.</p> | <p style="text-align: right;">Page 232</p> <p>1 Q Ulceration? 2 A Yes. 3 Q Bleeding? 4 A Very uncommonly. 5 Q And then if you're going to look at the 6 surgical treatments or therapies for prolapse, you 7 have vaginal approaches, abdominal approaches, 8 laparoscopic approaches, and robotic approaches; 9 correct? 10 A Laparoscopic approaches are abdominal 11 approaches. Robotic approaches are a subset of 12 laparoscopic approaches. 13 Q Have you ever done laparoscopic surgery 14 for prolapse? 15 A No. 16 Q Have you ever done robotic surgery for 17 prolapse? 18 A I am going to correct that last statement. 19 I have performed paravaginal repairs 20 laparoscopically. 21 Q On how many occasions? 22 A Perhaps 20 to 30. 23 Q Have you ever performed robotic surgery? 24 A No. 25 Q If one is evaluating the surgical</p> |
| <p style="text-align: right;">Page 231</p> <p>1 Q Oftentimes it may be that a woman has to 2 visit her doctor three or four times a year in order 3 to have the pessary removed and cleaned and to 4 consult with a doctor; correct? 5 A Correct. 6 Q Pessaries generally have to be removed 7 before sexual intercourse; correct? 8 A No. 9 Q There are those who recommend removal 10 before sexual intercourse, do they not? 11 A Are you speaking of physicians? 12 Q Yes. 13 A I can't speak to what all other physicians 14 would recommend. 15 Q Have you seen it reported in the 16 literature that one of the issues with the pessary 17 use is that it should be generally removed for 18 sexual intercourse? 19 A No. 20 Q Have you seen it reported in the 21 literature that pessaries may be associated with 22 vaginal discharge? 23 A Yes. 24 Q Odor? 25 A Yes.</p> | <p style="text-align: right;">Page 233</p> <p>1 treatment for prolapse, one of the considerations is 2 the type and severity of the prolapse that the woman 3 has? 4 A Yes. 5 Q The surgeon's training and experience? 6 A Yes. 7 Q The patient's preference for the type of 8 surgery after consultation with the physician? 9 A Yes. 10 Q And obviously the desired outcome; 11 correct? 12 A Yes. 13 Q For example, one of the surgeries that can 14 be performed for prolapse is obliterative surgery 15 that closes the vagina; correct? 16 A Correct. 17 Q And that would obviously be appropriate 18 generally only for those who don't seek to have 19 intercourse in the future? 20 A Correct. 21 Q When surgeons perform the surgeries, they 22 often choose different techniques in performing the 23 same surgeries, do they not? 24 MR. SLATER: Objection. 25 You can answer.</p> |

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| <p style="text-align: right;">Page 234</p> <p>1 THE WITNESS: There are standard 2 techniques of performing surgeries that surgeons may 3 vary. 4 BY MS. JONES: 5 Q And the surgeons vary based upon either 6 different approaches and what they feel comfortable 7 with or what they find to be satisfactory? 8 A Correct. 9 Q And as surgeons they may vary approaches 10 in the sense of being innovative in order to provide 11 better care to their patients? 12 A That is a complicated answer because the 13 line between innovation and experimentation is not 14 black and white. 15 Q Well, innovative approaches over time have 16 led to better healthcare in general, have they not? 17 A No, I wouldn't agree with that in general. 18 Q Would you agree that all surgeries have 19 risks? 20 A Yes. 21 Q That even in the absolute best of hands a 22 surgeon that there are complications that may not be 23 avoided? 24 A Yes. 25 Q If we talk about Ms. Gross, Ms. Gross had</p> | <p style="text-align: right;">Page 236</p> <p>1 determined that she needed an apical prolapse 2 procedure, I would have considered an iliococcygeal 3 muscle repair, possibly a uterosacral ligament 4 suspension; and if I decided she needed it, which 5 would probably be an intraoperative decision, an 6 enterocele repair. 7 Q How would you have counseled Ms. Gross in 8 advance of the surgery in terms of what her options 9 for treatment were? 10 A As we discussed, I would go over 11 behavioral and lifestyle changes, pelvic muscle 12 exercises, pessary use, and surgery. 13 Q And do you understand that all of those 14 were discussed with Ms. Gross? 15 A My recollection from the records is that a 16 pessary was discussed. I don't recall the 17 behavioral and lifestyle changes and exercises. 18 Q Do you recall that Ms. Gross was not 19 interested in a pessary? 20 A I recall that in the discussion with her 21 physician he was not enthusiastic it would be a good 22 solution for her. And in her experience she also 23 preferred not to choose a pessary. 24 Q What would you have discussed with 25 Ms. Gross about her surgical options?</p> |
| <p style="text-align: right;">Page 235</p> <p>1 had prior surgeries before she had the surgery 2 involving Prolift®, had she not? 3 A Correct. 4 Q Had some recurrent prolapse? 5 A She did not have recurrent prolapse. 6 Q She'd had a hysterectomy before? 7 A Correct. 8 Q That's one of the issues that you consider 9 when you determine what surgery would be 10 appropriate? 11 A I don't understand your question. 12 Q Is it appropriate to consider what prior 13 surgeries a patient has had before you determine 14 what surgery to perform to correct the prolapse? 15 A Of course, that's part of the patient's 16 history. I don't know that that necessarily 17 modifies the surgical approach to her current 18 prolapse problem. 19 Q Let me just ask you this: What options 20 would you have considered as Ms. Gross' surgeon to 21 correct her problems in 2006? 22 A Based on my understanding of her condition 23 at that time, with a Grade 3 to 4 rectocele and an 24 enterocele above that, I would have considered a 25 rectocele repair, a posterior colporrhaphy. If I</p> | <p style="text-align: right;">Page 237</p> <p>1 A I would have discussed the procedures I 2 named before and that at least part of the decision 3 would be based on the intraoperative findings. 4 Q And what would you have told her were the 5 complications associated with the surgery? 6 A As we discussed yesterday, the general 7 risks of any surgery: Bleeding, infection, risk of 8 anesthesia, complications that aren't directly 9 related to the surgical site but occur 10 postoperatively, like blood clots, pneumonia. 11 And then specific to the surgery, after 12 surgery pain with intercourse, voiding dysfunction. 13 I would mention the risk of ureteral injury since a 14 possibility would be uterosacral ligament 15 suspension, other organ injury that may need other 16 surgery to repair it. That's all I can think of at 17 the moment. 18 Q Would you discuss with her risk of damage 19 to the pudendal nerve? 20 A Nerve damage. I consider in the organ 21 tissue damage category nerve damage. I would only 22 specifically mention that if I were considering a 23 sacrospinous ligament fixation. 24 Q What would you have told her about the 25 possibility of recurrence?</p> |

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| <p style="text-align: right;">Page 238</p> <p>1 A That these operations aren't perfect, we 2 can't obviously guarantee 100 percent success, and 3 that there's a possibility that her problem could 4 come back. 5 Q And, in fact, about 30 percent of all 6 prolapse surgeries are for recurrence, aren't they? 7 A I don't think that's a reliable number. 8 Q That's certainly -- 9 A That's from one study. 10 Q That number's certainly been reported, has 11 it not? 12 A It's been reported to death. 13 Q And there have been different studies 14 which have reported recurrence rates as high and in 15 excess of 50 percent; correct? 16 A Recurrence, again, is a definition that's 17 undergone modification. At a time in the past when 18 anatomic outcomes were the focus, patients were 19 labeled as having recurrent prolapse when it passed 20 a certain arbitrary point in the POP-Q system. Many 21 of those women are asymptomatic, they don't need 22 subsequent surgery, they go on about their lives. 23 Q My question was, Doctor: Rates of 24 recurrence in excess of 50 percent have been 25 reported, have they not?</p> | <p style="text-align: right;">Page 240</p> <p>1 products? 2 A Not specifically, no. 3 Q Can you identify any transvaginal mesh 4 product that has more published clinical data than 5 Prolift®? 6 A I think the relevant point is that there 7 was no data on Prolift® at launch. 8 MS. JONES: Move to strike as 9 nonresponsive. 10 BY MS. JONES: 11 Q My question, Doctor, was: Can you 12 identify any transvaginal mesh product for whom 13 there is more published clinical data than on 14 Prolift®? 15 A This is 2012. It's an entirely different 16 situation. And Ethicon pulled Prolift® off the 17 market in the face of all this data because it was 18 not safe and not effective. 19 MS. JONES: Move to strike as 20 nonresponsive. 21 BY MS. JONES: 22 Q My question for the third time, Doctor, 23 is: Can you identify a single transvaginal mesh 24 product for which there is more published clinical 25 data than Prolift®?</p> |
| <p style="text-align: right;">Page 239</p> <p>1 A Correct. 2 Q Those have been reported out of the 3 Cleveland Clinic; correct? 4 A Correct. 5 Q Those were reported out of the Cleveland 6 Clinic when you were there; correct? 7 A It was certainly a study I co-authored. I 8 don't remember exactly when that was published, if I 9 had left the Cleveland Clinic by then. 10 Q But the patients in the study, patients 11 were treated and the study was conducted while you 12 were at the Cleveland Clinic? 13 A Correct. 14 Q You are aware, are you not, that the FDA 15 premarket notification process prior to 2005 did not 16 require original clinical studies to support the 17 clearance of surgical mesh; correct? 18 A Correct. 19 Q In the course of looking at and reviewing 20 these records, have you looked at any clinical data 21 that was used to support the clearance of the AMS 22 products Apogee® or Perigee®? 23 A Not specifically, no. 24 Q Had you ever looked at any clinical data 25 or ever seen any clinical data on those two</p> | <p style="text-align: right;">Page 241</p> <p>1 A No. 2 Q Can you identify other than Prolift® any 3 transvaginal mesh product for whom there is more 4 published data than Gynemesh® PS? 5 A No. 6 Q Have you reviewed, Doctor, any of the 7 preclinical bench or animal studies done on the 8 Prolene® PS or the Prolene® mesh? 9 A The Gynemesh® PS mesh? 10 Q Or the Gynemesh® PS mesh. 11 A Yes. 12 Q What studies have you reviewed? 13 A The animal studies in a rat model looking 14 at mesh implantation in an abdominal location for 15 short-term histologic changes. 16 Q I think I asked you this yesterday. But 17 I'm not certain. Have you yourself actually ever 18 performed any animal studies? 19 A I have assisted the fellows in their work 20 with Dr. Moalli at the University of Pittsburgh in 21 her studies of -- in her animal studies. And at the 22 Cleveland Clinic I supervised the fellows in the 23 performance of their research with animals. 24 Q Have you ever actually implanted mesh in 25 an animal?</p> |

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| <p style="text-align: right;">Page 242</p> <p>1 A No.</p> <p>2 Q Have you ever actually taken mesh out of</p> <p>3 an animal and examined it pathologically?</p> <p>4 A I have not taken mesh out of an animal. I</p> <p>5 have examined it pathologically.</p> <p>6 Q The tissues from the animal?</p> <p>7 A Yes.</p> <p>8 Q Have you ever published on any of those</p> <p>9 animal review studies?</p> <p>10 A They have been published. I am not a</p> <p>11 co-author.</p> <p>12 Q Doctor, have you ever performed any</p> <p>13 studies to evaluate the foreign body response to any</p> <p>14 mesh?</p> <p>15 A No.</p> <p>16 Q What is your understanding of the size of</p> <p>17 a microphage?</p> <p>18 A I'm sorry?</p> <p>19 Q Do you know what the size of a microphage</p> <p>20 is?</p> <p>21 MR. SLATER: A macrophage?</p> <p>22 THE WITNESS: Macrophage? Macrophage</p> <p>23 is what you're saying?</p> <p>24 BY MS. JONES:</p> <p>25 Q Yes, yes.</p> | <p style="text-align: right;">Page 244</p> <p>1 A Yes.</p> <p>2 Q Ever had any difficulties with use of</p> <p>3 those sutures?</p> <p>4 A Difficulties like what?</p> <p>5 Q I'm asking you, Doctor.</p> <p>6 MR. SLATER: She's asking you to</p> <p>7 define what you mean by "difficulties." It's a</p> <p>8 pretty ambiguous term, which I object to.</p> <p>9 BY MS. JONES:</p> <p>10 Q You can't answer that question, Doctor?</p> <p>11 MR. SLATER: Can you refine what you</p> <p>12 mean by "difficulties"?</p> <p>13 MS. JONES: I'm asking the doctor</p> <p>14 whether she can answer the question.</p> <p>15 MR. SLATER: She already asked you to</p> <p>16 define the term so I don't understand why you won't</p> <p>17 do it.</p> <p>18 MS. JONES: Because I'm asking the</p> <p>19 questions, counsel.</p> <p>20 MR. SLATER: Okay. But she's already</p> <p>21 asked you to refine what you mean. So normally when</p> <p>22 you're taking a deposition and the witness says I</p> <p>23 don't know what you mean, you refine the question.</p> <p>24 MS. JONES: This is the first</p> <p>25 deposition I've ever taken, Doctor -- I mean,</p> |
| <p style="text-align: right;">Page 243</p> <p>1 A Macrophage is in the range of 10 to</p> <p>2 20 microns.</p> <p>3 Q Do you know what the size of a leukocyte</p> <p>4 is?</p> <p>5 A Macrophages are in the family of</p> <p>6 leukocytes, so, yes, 10 to 20 microns.</p> <p>7 Q Have you ever seen any criticism by the</p> <p>8 FDA of the pore size of the Gynemesh® PS or the</p> <p>9 porosity of the Gynemesh PS?</p> <p>10 MR. SLATER: Can I have that question</p> <p>11 read back? I might have missed something there.</p> <p>12 (The court reporter read the record</p> <p>13 as follows:</p> <p>14 "QUESTION: Have you ever seen any</p> <p>15 criticism by the FDA of the pore size of the</p> <p>16 Gynemesh® PS or the porosity of the Gynemesh PS?")</p> <p>17 MR. SLATER: Objection; assumes the</p> <p>18 issue was even ever looked at by the FDA.</p> <p>19 You can answer.</p> <p>20 THE WITNESS: Not to my knowledge.</p> <p>21 BY MS. JONES:</p> <p>22 Q Have you used polypropylene sutures in</p> <p>23 your surgeries?</p> <p>24 A Yes.</p> <p>25 Q Since the time you were in your residency?</p> | <p style="text-align: right;">Page 245</p> <p>1 counsel.</p> <p>2 MR. SLATER: If you're going to start</p> <p>3 calling me Dr. Slater, okay, you're not going to be</p> <p>4 the first one. It's a big step up for me. Wow.</p> <p>5 BY MS. JONES:</p> <p>6 Q Have you ever filed an adverse experience</p> <p>7 report with respect to polypropylene sutures?</p> <p>8 A No.</p> <p>9 Q Have you ever reported anywhere any</p> <p>10 degradation with polypropylene sutures?</p> <p>11 A No.</p> <p>12 Q Have you ever seen any evidence of</p> <p>13 degradation in your surgeries?</p> <p>14 A No.</p> <p>15 Q In terms of the mesh that you used in</p> <p>16 abdominal sacrocolpopexy, have you ever seen</p> <p>17 evidence of degradation there?</p> <p>18 A I wouldn't see evidence of degradation</p> <p>19 because it's -- if it's going on, it's going on in</p> <p>20 the patient's body.</p> <p>21 Q Have you ever seen any removed mesh,</p> <p>22 Doctor, that shows any evidence of degradation?</p> <p>23 A Yes.</p> <p>24 Q When did you see that?</p> <p>25 A In my review of the medical literature.</p> |

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| <p style="text-align: right;">Page 246</p> <p>1 Q My question, Doctor, was whether or not 2 you had actually seen mesh that showed any evidence 3 of degradation. 4 A I believe I answered your question. 5 Q You've held mesh that shows evidence of 6 degradation? 7 A You didn't ask me if I held it. 8 Q Let's see if we can get on the same 9 wavelength. 10 MR. SLATER: Whatever you do, don't 11 get on the same wavelength. 12 BY MS. JONES: 13 Q I'm asking you, Doctor, whether or not you 14 have held in your hands any polypropylene mesh of 15 which you decided or could discern any evidence of 16 degradation. 17 A No. 18 Q Have you ever had a patient who had a 19 failure of mesh that you attributed to degradation? 20 A I can't say -- I can't say. I can't say 21 no for sure. Patients experience failure and it's 22 possible that it's due to suture breakage, which 23 would be due to suture degradation. 24 Q All right. Maybe we miscommunicated. I 25 was asking you about the mesh itself this time.</p> | <p style="text-align: right;">Page 248</p> <p>1 retrospective chart reviews. I don't recall seeing 2 any prospective research. 3 Q Do you recall reviewing any biomaterials 4 literature at that time with respect to the 5 characteristics of polypropylene? 6 A I may have. I can't say for sure. 7 Q Do you remember reviewing any literature 8 with respect to the historical use of polypropylene 9 in the body? 10 A I would expect so. 11 Q Well, can you tell me as you sit here 12 today when polypropylene was first used in the body? 13 A I believe it was in the '50s or '60s. 14 Q Do you know when polypropylene mesh was 15 first used in the body? 16 A I believe in that same time, '50s or '60s. 17 Q As you sit here today, Doctor, can you 18 identify any alternative mesh product that you 19 believe is a better product for use to treat 20 prolapse than Gynemesh® PS? 21 A I don't believe mesh of any type in the 22 polypropylene family is an appropriate choice for 23 transvaginal mesh implantation. 24 Q Let me ask the question a little bit 25 differently. Can you identify for me any type of</p> |
| <p style="text-align: right;">Page 247</p> <p>1 MR. SLATER: What's the question? 2 She must have misunderstood. 3 MS. JONES: I asked her whether or 4 not she had ever had a failure of mesh in a patient 5 that she attributed to degradation. 6 THE WITNESS: No. 7 BY MS. JONES: 8 Q Prior to becoming or being retained as an 9 expert in this litigation, is it fair to say that 10 you had not previously reviewed the literature on 11 polypropylene? 12 A In my experience as the program director 13 for the pelvic floor disorders network, we were 14 considering the design of a trial using mesh. At 15 that time I would have reviewed the literature to 16 understand what had been done with mesh products and 17 what other research was needed. 18 Q What can you remember about your review of 19 the literature at that time specifically as it 20 relates to polypropylene mesh? 21 A The literature was lacking. 22 Q What can you remember about your review of 23 the literature at that time with respect to 24 polypropylene mesh? 25 A There may have been case series and</p> | <p style="text-align: right;">Page 249</p> <p>1 mesh that you believe is appropriate for use 2 transvaginally? 3 A Based on my background and my study, my 4 conclusion is that any mesh placed transvaginally 5 for prolapse exceeds -- the risks far exceed the 6 benefit. 7 Q Am I correct then, Doctor, that you, as 8 you sit here today, cannot identify for us an 9 alternative mesh to Prolift® for use transvaginally 10 to repair prolapse? 11 A You're suggesting an alternative is 12 necessary. I don't agree with that. 13 Q I'm just asking you, Doctor, whether or 14 not you can identify one. 15 MR. SLATER: Well, let me just ask 16 what the question means. She just told you she 17 doesn't think any of the meshes should be used. So 18 when you say can you identify one, are you asking 19 her to just list them? 20 MS. JONES: Could we not have 21 speaking objections? 22 MR. SLATER: Well, I object to the 23 form. It's incredibly ambiguous, the question. 24 Could you rephrase it? 25 MS. JONES: How about let me conduct</p> |

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| <p style="text-align: right;">Page 250</p> <p>1 this and you just say objection, as I have done at 2 your depositions, and we'll be in good shape. 3 MR. SLATER: Well, you went a little 4 past the word "objection," with all due respect, so 5 I think the question is extremely confusing and 6 ambiguous. 7 BY MS. JONES: 8 Q I'm asking you, Doctor, this question: 9 You have told us that you do not consider any mesh 10 to be appropriately used for the transvaginal 11 treatment of prolapse; is that correct? 12 A I believe I said polypropylene mesh or 13 mesh in the polypropylene family. 14 Q All right. That's what I thought you 15 said. So can you tell me then of any mesh that can 16 be appropriately used transvaginally? 17 A I don't believe such a product exists. 18 Q So it's fair to say that while you're 19 saying polypropylene mesh should not be used, that 20 you're not suggesting that there is a better 21 alternative mesh than polypropylene? 22 A I don't agree with your use of the word 23 "alternative." 24 Q Well, I'm trying to understand your 25 opinions, Doctor. So what I'm asking you is,</p> | <p style="text-align: right;">Page 252</p> <p>1 through the 510(k) process, which in my opinion is 2 inadequate to demonstrate the safety of these 3 meshes. 4 MS. JONES: Move to strike as 5 nonresponsive. 6 BY MS. JONES: 7 Q My question, Doctor, was this: Is it your 8 testimony and your opinion that no mesh should be on 9 the market for the transvaginal treatment of 10 prolapse? 11 A My opinion is that if a mesh belongs on 12 the market for the transvaginal treatment of 13 prolapse, the safety needs to be established first. 14 MS. JONES: Move to strike as 15 nonresponsive. 16 BY MS. JONES: 17 Q As we sit here today, Doctor, is it your 18 opinion that no mesh used for transvaginal treatment 19 of prolapse should be on the market? 20 A I believe I answered that question. To my 21 understanding, all of the products currently on the 22 market have gone through 510(k) process, which in my 23 opinion is insufficient to establish their safety. 24 If they're not safe, they don't belong on the 25 market.</p> |
| <p style="text-align: right;">Page 251</p> <p>1 there a better mesh of which you are aware than the 2 polypropylene mesh? 3 A A yes or no answer would not -- would be 4 misleading. You're suggesting that there's a 5 comparison to be made. I can use the words of one 6 of Ethicon's own employees: The best of a bad lot, 7 talking about polypropylene. 8 MS. JONES: Move to strike as 9 nonresponsive. 10 BY MS. JONES: 11 Q My question, Doctor, doesn't relate to 12 polypropylene. My question relates to whether or 13 not you have an opinion that there is a mesh that 14 has better characteristics for implantation in the 15 body than polypropylene. 16 A I have answered that I don't believe a 17 mesh exists that's appropriate for transvaginal 18 implantation for Prolift® -- prolapse. Excuse me. 19 Q So it would be your opinion that no mesh 20 should be on the market for the transvaginal 21 treatment of prolapse? 22 A I believe that the mesh -- let me start 23 again. The greater part of my knowledge revolves 24 around Gynemesh® PS mesh used in Prolift®. To my 25 understanding, every product on the market went</p> | <p style="text-align: right;">Page 253</p> <p>1 Q So your opinion is that no mesh currently 2 used for the transvaginal treatment of prolapse 3 should be on the market? 4 A I believe I answered that question. 5 Q I'm just asking you, Doctor, am I correct 6 that that is your opinion? 7 A I don't believe that -- I believe I've 8 answered that question and I don't believe that 9 question can be answered with a simple yes or no. 10 Q Well, tell me then, Doctor, identify for 11 me as you sit here today the mesh that you believe 12 should be on the market for the transvaginal 13 treatment of prolapse. 14 A I already told you I don't believe that 15 mesh exists at this point in time. 16 Q Do you know how many doctors in this 17 country have used polypropylene mesh for the 18 transvaginal treatment of prolapse? 19 A No. 20 Q You do know that a significant number of 21 surgeons in this country have used transvaginal mesh 22 for the treatment of prolapse; correct? 23 A I know that a significant number of 24 surgeons have used mesh and have abandoned it 25 because they believe it's too unsafe to be used in</p> |

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| <p style="text-align: right;">Page 254</p> <p>1 their patients.</p> <p>2 Q You know that not every woman who has had</p> <p>3 transvaginal mesh used to correct prolapse has</p> <p>4 experienced complications, don't you?</p> <p>5 A Not yet. These women are at lifelong risk</p> <p>6 for complications from the permanent implantation of</p> <p>7 Prolift® mesh.</p> <p>8 Q Based upon the studies and the literature</p> <p>9 that are out there, 75 to 80 percent of the women</p> <p>10 who have transvaginal mesh used to correct prolapse</p> <p>11 have had no major complications; correct?</p> <p>12 A Not yet. There is no safe time -- one of</p> <p>13 your experts in the medical literature -- there is</p> <p>14 no safe time after mesh implantation for eliminating</p> <p>15 the risk of complications.</p> <p>16 MS. JONES: Move to strike as</p> <p>17 nonresponsive.</p> <p>18 BY MS. JONES:</p> <p>19 Q As we sit here today, today, Doctor, 75 to</p> <p>20 80 percent of the women who have had transvaginal</p> <p>21 mesh correction of Prolift® have experienced no</p> <p>22 significant, major complications; correct?</p> <p>23 MR. SLATER: Objection.</p> <p>24 THE WITNESS: Where do you get the --</p> <p>25 MR. SLATER: You can go ahead.</p> | <p style="text-align: right;">Page 256</p> <p>1 complications noted in the studies, whether it's</p> <p>2 case studies or randomized trials, does it not?</p> <p>3 A It may. It may not be complete or</p> <p>4 accurate. For example, in the TVM studies that were</p> <p>5 published, the five-year study that was published in</p> <p>6 the medical literature is inaccurate and does not</p> <p>7 accurately provide the extent of complications</p> <p>8 experienced by women who had the TVM procedure.</p> <p>9 Q As I recall, Doctor, you have never</p> <p>10 examined a woman that's had Prolift®; is that</p> <p>11 correct?</p> <p>12 A That is correct.</p> <p>13 Q Have you ever spoken with a woman that's</p> <p>14 had Prolift®?</p> <p>15 A It's not on her forehead.</p> <p>16 Q I'm sorry?</p> <p>17 A It's not on her forehead. Not to my</p> <p>18 knowledge.</p> <p>19 Q Have you ever done --</p> <p>20 MR. SLATER: Do you want to take a</p> <p>21 break?</p> <p>22 THE WITNESS: Is this a good time for</p> <p>23 a break?</p> <p>24 MR. SLATER: If you need a break,</p> <p>25 it's a good time.</p> |
| <p style="text-align: right;">Page 255</p> <p>1 THE WITNESS: Where do you get the 75</p> <p>2 to 80 percent?</p> <p>3 BY MS. JONES:</p> <p>4 Q Well, let me just ask you first, do you</p> <p>5 agree with that? That's my question.</p> <p>6 A I would like to know the basis for your</p> <p>7 question. I would like to know the basis for which</p> <p>8 you claim that 75 to 80 percent of women after</p> <p>9 Prolift® implantation have not had significant,</p> <p>10 major complications.</p> <p>11 Q You know, Doctor, I get to ask the</p> <p>12 questions here.</p> <p>13 A And I get to have the questions clarified.</p> <p>14 Q Well, my question to you is do you agree</p> <p>15 with that figure or not?</p> <p>16 A I am not going to agree with that</p> <p>17 statement on the basis of a lack of clarification.</p> <p>18 Q Have you looked at the medical literature</p> <p>19 with respect to the use of transvaginal mesh?</p> <p>20 A Short term.</p> <p>21 Q My question, Doctor, is have you looked at</p> <p>22 the medical literature with respect to the use of</p> <p>23 transvaginal mesh?</p> <p>24 A Yes.</p> <p>25 Q And that medical literature reports on</p> | <p style="text-align: right;">Page 257</p> <p>1 BY MS. JONES:</p> <p>2 Q Let me ask this question first. Have you</p> <p>3 ever done any separate analysis, Doctor, of any</p> <p>4 literature regarding Prolift® complications?</p> <p>5 MR. SLATER: What do you mean by a</p> <p>6 "separate analysis"? Beyond what she's done in this</p> <p>7 case?</p> <p>8 THE WITNESS: What do you mean by</p> <p>9 "separate analysis"?</p> <p>10 BY MS. JONES:</p> <p>11 Q Have you ever sat down, Doctor, and done a</p> <p>12 meta-analysis of studies involving Prolift®?</p> <p>13 A No.</p> <p>14 MS. JONES: Let's take a break.</p> <p>15 (Short recess.)</p> <p>16 BY MS. JONES:</p> <p>17 Q Doctor, in your reports that outline your</p> <p>18 opinions in this case, have you set forth your</p> <p>19 criticisms of the medical literature and the</p> <p>20 individual studies?</p> <p>21 A Yes.</p> <p>22 Q To the best of your knowledge as you sit</p> <p>23 here today, have you identified all of those</p> <p>24 criticisms?</p> <p>25 A Yes.</p> |

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| <p style="text-align: right;">Page 258</p> <p>1 Q If we turn to the instructions for use for 2 Prolift®, you have opinions about the adequacy of 3 the warnings that were included within them; am I 4 correct? 5 A Yes. 6 Q Can you tell me, Doctor, or just summarize 7 for me, if you would, your opinions of what should 8 have been in the IFU in terms of complications that 9 were not in there and when they should have been 10 included? 11 MR. SLATER: Do you mind if she has 12 her report available or the IFU available? Because 13 she has nothing in front of her right now. 14 MS. JONES: I understand. And I will 15 stipulate to you that whatever is in the report is 16 in the report. I'm not trying to trick you. I'm 17 just trying to move quickly through this. 18 MR. SLATER: Because it's kind of 19 hard to remember everything sitting here. 20 THE WITNESS: I would prefer to have 21 my report. 22 MS. JONES: Then you're more than 23 welcome. 24 MR. SLATER: Unless counsel might 25 want you to just throw out a couple and she's just</p> | <p style="text-align: right;">Page 260</p> <p>1 when they should have been included?") 2 THE WITNESS: Well, I can answer the 3 last part of the question first. Clearly they 4 should have been included from the moment Prolift® 5 was on the market. 6 BY MS. JONES: 7 Q While you're looking for that, Doctor, is 8 it your testimony that you believe that every 9 potential complication associated with the use of 10 Prolift® was known at the time that it was first 11 marketed? 12 A I understand that was the testimony of 13 Ethicon employees; yes. 14 Q I was asking really for your opinion at 15 the time. 16 A No. My opinion at the time was that all 17 of the risks were not known and that evolved over 18 time. In fact -- 19 Q How do you understand that those risks -- 20 A -- the treating physicians of the 21 plaintiffs testified that they learned over time 22 several of the contraindications and additional 23 risks that Ethicon failed to inform them of. 24 Q What is your understanding of how that 25 evolved over time?</p> |
| <p style="text-align: right;">Page 259</p> <p>1 going to ask you questions about the few that you 2 come up with now as long as we understand -- 3 MS. JONES: If you want to have your 4 report, you can have it. I was, frankly, just 5 trying to move along quickly in the hopes we could 6 finish today. I'm not trying to put anybody at a 7 disadvantage. 8 MR. SLATER: I'm fine with doing 9 this. I just don't want it to be construed later 10 that her testimony was some complete list. That's 11 all. As long as we have that understanding, it's 12 fine. It's up to you. 13 MS. JONES: I'm willing to say that 14 whatever's in the report is in the report. I'm not 15 trying to trick you in any way, shape, or form. But 16 I'm also willing to let you have the report and go 17 through it. 18 THE WITNESS: Could you repeat the 19 question, please? 20 (The court reporter read the record 21 as follows: 22 "QUESTION: Can you tell me, Doctor, 23 or just summarize for me, if you would, your 24 opinions of what should have been in the IFU in 25 terms of complications that were not in there and</p> | <p style="text-align: right;">Page 261</p> <p>1 A My understanding is that patients with 2 preexisting chronic pain conditions are 3 contraindicated to undergo the Prolift® procedure 4 because they are at such higher risk of developing 5 either an exacerbation of their preexisting 6 condition or the development of a new pain condition 7 and that was not warned of at the time of Prolift® 8 launch. 9 Q Let me ask you this, Doctor: In terms of 10 women with a chronic pain condition, those women 11 would be at increased risk of pelvic pain regardless 12 of the type of surgery that was performed, would 13 they not? 14 A That is not my clinical experience. 15 Q In the course of your clinical experience, 16 did you perform prolapse surgery on patients with a 17 chronic pain syndrome? 18 A Yes. 19 Q Tell me what types of chronic pain 20 syndrome you would perform surgery on. 21 A Fibromyalgia, arthritis, migraine 22 headaches. That's all I can think of at the moment. 23 Q Do you have any idea as you sit here today 24 how many women you performed prolapse surgery on who 25 had fibromyalgia?</p> |

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| <p style="text-align: right;">Page 262</p> <p>1 A I do not know.</p> <p>2 Q How about how many women had migraine</p> <p>3 headaches?</p> <p>4 A I do not know.</p> <p>5 Q Did you take any special precautions for</p> <p>6 women who had chronic pain syndrome?</p> <p>7 A I counseled them that in the immediate</p> <p>8 postoperative period they may experience more pain</p> <p>9 and we will do everything we can to manage that</p> <p>10 effectively for them. Outside of the immediate four</p> <p>11 to six weeks after surgery, that should have</p> <p>12 resolved to baseline.</p> <p>13 Q Did you counsel all women whom you knew</p> <p>14 had had chronic pain conditions about that?</p> <p>15 A That would have been my practice.</p> <p>16 Q Is that something that you think would be</p> <p>17 a standard practice for surgeons performing prolapse</p> <p>18 surgery?</p> <p>19 A I don't want to speak for all surgeons</p> <p>20 performing prolapse surgery.</p> <p>21 Q Is that something that you trained your</p> <p>22 residents to do?</p> <p>23 A Yes.</p> <p>24 Q Is that something that you trained your</p> <p>25 fellows to do?</p> | <p style="text-align: right;">Page 264</p> <p>1 pain conditions?</p> <p>2 Q I am, if that's what you would --</p> <p>3 A Okay. To the best of my recollection at</p> <p>4 the moment, I already mentioned fibromyalgia,</p> <p>5 arthritis -- I can't remember the third thing I</p> <p>6 said.</p> <p>7 Q You said migraines.</p> <p>8 A Migraines. Thank you. Interstitial</p> <p>9 cystitis, endometriosis. Many chronic pain</p> <p>10 syndromes don't have a diagnosis. They are</p> <p>11 described as a chronic pain syndrome. I'm trying to</p> <p>12 give you a list of the conditions that actually have</p> <p>13 a diagnosis.</p> <p>14 Q Well, can you give me some -- other than</p> <p>15 what you've already given, are there other examples</p> <p>16 of complaints that women had experienced that would</p> <p>17 prompt you to have the conversation with them about</p> <p>18 chronic pain and any increased risk?</p> <p>19 A Pelvic muscle spasm. I can't think of any</p> <p>20 other conditions at this time.</p> <p>21 Q If you became aware as a physician that a</p> <p>22 patient had complained of significant pain following</p> <p>23 earlier surgical procedures, would you have</p> <p>24 counseled them on that?</p> <p>25 MR. SLATER: Objection; ambiguous.</p> |
| <p style="text-align: right;">Page 263</p> <p>1 A Yes.</p> <p>2 Q Is that something that you did beginning</p> <p>3 in the course of your residency?</p> <p>4 A I don't remember that specifically.</p> <p>5 Q When did you begin to counsel patients</p> <p>6 about chronic pain syndromes?</p> <p>7 A That would have been in my residency when</p> <p>8 they were surgical candidates.</p> <p>9 Q So from the time you were in your</p> <p>10 residency, you would have counseled patients on</p> <p>11 those chronic pain situations?</p> <p>12 A Correct.</p> <p>13 Q And that was something that you were</p> <p>14 trained to do in your residency?</p> <p>15 A Correct.</p> <p>16 Q And what do you consider to be chronic</p> <p>17 pain conditions or syndromes?</p> <p>18 A I don't understand your question. Are you</p> <p>19 asking again for a list of chronic pain conditions?</p> <p>20 Q I am.</p> <p>21 A All chronic pain conditions?</p> <p>22 Q What I'm asking for is a list, Doctor, of</p> <p>23 the conditions that would prompt you to counsel</p> <p>24 patients about that.</p> <p>25 A So you're asking for a list of all chronic</p> | <p style="text-align: right;">Page 265</p> <p>1 You can answer.</p> <p>2 THE WITNESS: Significant pain that</p> <p>3 became chronic?</p> <p>4 BY MS. JONES:</p> <p>5 Q That's what I'm trying to ask you. I'm</p> <p>6 trying to understand under what circumstances you</p> <p>7 would counsel patients on chronic pain and any</p> <p>8 increased risk.</p> <p>9 MR. SLATER: Objection; ambiguous.</p> <p>10 You can answer.</p> <p>11 THE WITNESS: I don't know that I can</p> <p>12 add to the list I've already given you.</p> <p>13 BY MS. JONES:</p> <p>14 Q But you would counsel patients about that</p> <p>15 regardless of the type of prolapse surgery that you</p> <p>16 were going to perform?</p> <p>17 MR. SLATER: Objection.</p> <p>18 You can answer.</p> <p>19 THE WITNESS: Yes, yes.</p> <p>20 BY MS. JONES:</p> <p>21 Q I mean, it didn't make any difference</p> <p>22 whether it was a vaginal sacrospinal ligament</p> <p>23 fixation or an abdominal sacrocolpopexy?</p> <p>24 A Correct.</p> <p>25 Q Other than the chronic pain syndrome that</p> |

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| <p style="text-align: right;">Page 266</p> <p>1 you just mentioned, are there other complications 2 that you believe should have been included within 3 the IFU at the time of launch? 4 A Infection potentiation was included as a 5 risk and that is an inadequate statement to -- 6 Q I'm sorry. What -- 7 A Oh, Page 405. And that is an inadequate 8 description of the nature and extent and severity of 9 the kinds of infectious complications that can occur 10 after the Prolift® procedure and permanent Prolift® 11 mesh implantation. 12 Q Can you identify for me, Doctor, any 13 studies that show a statistical significant 14 increased risk of infection associated with 15 Prolift®? 16 A There are two types of infections. The 17 first type of infection is an acute infection, an 18 abscess, as an example. And to my knowledge, that 19 type of infection has not been increased after 20 Prolift® procedures. 21 The second type of infection is a chronic 22 low-grade infection, and that is something that 23 occurs more commonly after Prolift® surgery than 24 after native tissue repair. 25 Q And can you tell me what study you're</p> | <p style="text-align: right;">Page 268</p> <p>1 A I don't think I would label it a 2 hypothesis. 3 Q Then can you identify for me a study that 4 shows a statistically significant increased risk of 5 a low-grade infection? 6 A Mesh erosion. 7 Q I'm asking you for a study. Can you just 8 identify for me what it is that you're relying upon 9 when you make those comments? 10 MR. SLATER: With all due respect, 11 I'm not going to go through what she said -- and 12 you're tilting your head at me -- but, you know, 13 she's given you a very, very specific answer and 14 given you chapter and verse on a whole extent of 15 literature. 16 MS. JONES: Counsel, I've asked four 17 times -- 18 MR. SLATER: And you've gotten a 19 direct answer. 20 MS. JONES: I have asked four times 21 for the identification of a study and we don't have 22 a study that's been identified yet. If there's not 23 one, there's not one. 24 BY MS. JONES: 25 Q I'm just asking what it is specifically</p> |
| <p style="text-align: right;">Page 267</p> <p>1 relying upon when you say that? 2 A Because Ethicon failed to study the 3 etiology of mesh erosion, the etiology is not 4 completely understood. Surgeons believe that a 5 chronic low-grade infection is responsible for mesh 6 erosion and recurrent mesh erosion. And in that way 7 that is an example of a chronic low-grade infection 8 that can only occur after mesh implantation and 9 specifically Prolift®. 10 Q Doctor, my question was really can you 11 identify specifically for me what you're relying 12 upon when you make those statements? 13 A All of the articles that demonstrate at 14 least a 10 percent -- not at least -- an average of 15 10 percent and many studies showing much higher 16 rates of mesh erosion. 17 Q Erosion, not infection, erosion? 18 A Again, because the etiology is not 19 understood because Ethicon failed to study this, 20 mesh -- surgeons are still trying to figure out what 21 causes mesh erosion. And it's plausible from a 22 biological standpoint that these are low-grade 23 subclinical infections and are causing mesh erosion 24 and recurrent mesh erosion. 25 Q And that is a hypothesis at this point?</p> | <p style="text-align: right;">Page 269</p> <p>1 that you rely upon. What is it that you rely upon 2 for those statements? 3 A The Altman study didn't even report the 4 number of patients who experienced mesh erosion. It 5 reported the number of patients who required surgery 6 for mesh erosion. Every single study of Prolift® in 7 the literature identifies that specific rate of mesh 8 erosion in that study. That's the studies -- those 9 are the studies I am relying on. 10 Q So you're relying on erosion as being 11 identical to infection? 12 A To the best of my understanding in 2012, 13 because Ethicon failed to study this and understand 14 the etiology of mesh erosion before they put the 15 Prolift® or even the Gynemesh® PS mesh on the 16 market, etiology of mesh erosion is not completely 17 understood. To my understanding, the most logical 18 explanation is a subclinical low-grade infection 19 because the mesh is contaminated on placement and 20 that contamination cannot be cleared. It shows 21 itself as mesh erosion and recurrent mesh erosion. 22 MS. JONES: Move to strike as 23 nonresponsive. 24 BY MS. JONES: 25 Q Doctor, tell me, if you would, what you</p> |

15 (Pages 266 to 269)

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| <p style="text-align: right;">Page 270</p> <p>1 rely upon in support of your opinion that a 2 subclinical infection causes mesh erosion. 3 MR. SLATER: In addition to what she 4 just told you, counsel? 5 MS. JONES: I'm just asking her to 6 tell me. 7 MR. SLATER: Hang on. It's asked and 8 answered. So I'm asking you do you want her to 9 repeat what she said or in addition to what she 10 said? 11 MS. JONES: I want her to tell me 12 what she relies upon specifically -- 13 MR. SLATER: She just told you. 14 MS. JONES: -- for the opinion that a 15 subclinical infection causes erosion. 16 MR. SLATER: And you were asking in 17 the literature. Now it goes beyond the literature? 18 She can bring out anything else? 19 MS. JONES: I've never gotten 20 anything out of the literature. 21 MR. SLATER: Well, you have. She 22 listed every single Prolift® study with erosion 23 rates. 24 MS. JONES: Counsel, come on. It's 25 inappropriate.</p> | <p style="text-align: right;">Page 272</p> <p>1 erosion? 2 A In addition -- 3 MR. SLATER: Same objection. 4 You can answer again. 5 THE WITNESS: In addition to all the 6 evidence in the medical literature, I rely on the 7 experience and opinion of surgeons who are 8 experienced in caring for women who have mesh 9 erosion and recurrent mesh erosion and who have 10 studied this over their years of clinical practice 11 in order to somehow find a better way to treat these 12 women, because we don't -- 13 BY MS. JONES: 14 Q Can you name those surgeons for me? 15 A Dr. Shlomo Raz. 16 Q Anybody else? 17 A I don't remember his name. He is the 18 infectious disease expert from the University of 19 Connecticut. 20 Q Okay. The infectious disease expert in 21 this litigation? 22 A Yes. 23 Q Anybody else? 24 A That's all I can think of off the top of 25 my head.</p> |
| <p style="text-align: right;">Page 271</p> <p>1 MR. SLATER: It's not inappropriate. 2 She said it three times. 3 MS. JONES: It is inappropriate. And 4 I don't want to go to the judge, but even the judge 5 is going to recognize these are speaking objections. 6 We've got an expert witness here who can answer the 7 questions. This is inappropriate. 8 MR. SLATER: Well, it's 9 inappropriate, too, for counsel to pretend that an 10 answer hasn't been given and to continue to ask the 11 same question because you don't like the answer. 12 MS. JONES: No, I haven't gotten the 13 answer. And we can look at it and we can ask Judge 14 Higbee to look at it. 15 MR. SLATER: You have the right to do 16 that. I feel very confident that what I'm doing is 17 appropriate right now. 18 MS. JONES: Well, I don't think it's 19 appropriate, what Judge Higbee thinks is 20 appropriate. So I'm going to ask the question one 21 more time. 22 BY MS. JONES: 23 Q I'd like, Doctor, for an answer to the 24 question. Specifically what is it upon which you 25 rely that says a subclinical infection causes</p> | <p style="text-align: right;">Page 273</p> <p>1 Q Do you believe, Doctor, and is it your 2 opinion that the erosions associated with 3 transvaginal mesh are different from the erosions 4 with other mesh? 5 MR. SLATER: Objection to the form. 6 You can answer. 7 Highly ambiguous. 8 You can answer. 9 THE WITNESS: Yes. 10 BY MS. JONES: 11 Q How? 12 A The mesh is implanted through what is 13 termed surgically a clean contaminated environment. 14 It's laden with bacteria from the moment it's in the 15 woman's body. 16 Q That's with the transvaginal mesh? 17 A Correct. 18 Q What causes erosion in the mesh used in 19 abdominal sacrocolpopexy? 20 A The characteristics of the mesh incite an 21 inflammatory reaction and foreign body reaction that 22 disturbs the surrounding tissue and results in the 23 formation of an erosion. 24 Q And that's different from what happens 25 with a transvaginal mesh?</p> |

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| <p style="text-align: right;">Page 274</p> <p>1 A Are you asking me to differentiate 2 abdominal sacrocolpopexy? 3 Q I'm asking you how the erosions that occur 4 with meshes not used in transvaginal surgery are 5 caused and how those differ from what's used in 6 transvaginal surgery. 7 MR. SLATER: Objection to the form. 8 You can answer. 9 THE WITNESS: First of all, in 10 abdominal sacrocolpopexy the mesh is placed on the 11 outside of the vagina from an internal basis. In 12 transvaginal mesh implantation, the vagina is 13 incised, dissected, creating whatever level of 14 tissue damage occurs with incisions and dissection. 15 And, as I said, the mesh is contaminated in 16 placement because of the natural vaginal 17 microenvironment that cannot be sterilized at the 18 time of surgery. The surgical field cannot be 19 separated, draped in such a way as to isolate a 20 specific area that you're operating on in order to 21 prevent the introduction of bacteria with mesh 22 implantation. That's one reason. 23 BY MS. JONES: 24 Q I'm sorry, Doctor. We're just not 25 communicating. If you have mesh that's used in</p> | <p style="text-align: right;">Page 276</p> <p>1 things that you've noted and say you have completely 2 set out your opinions here in your report? 3 A My opinions are completely set out in my 4 report. 5 MR. SLATER: Obviously, counsel, 6 there are supplemental reports, too. 7 BY MS. JONES: 8 Q Doctor, have you ever talked with or 9 visited with a surgeon who has used Prolift® to 10 treat women? 11 A You mean specific to the Prolift®? 12 Q Yes, ma'am. 13 A No. 14 Q Have you ever spoken with a doctor who has 15 gone through the Prolift® professional education 16 program about that program? 17 A No. 18 Q Have you ever spoken with a doctor who has 19 gone through either a proctorship or a preceptorship 20 with respect to Prolift®? 21 A No. 22 Q Have you ever attended any professional 23 meetings where studies with respect to Prolift® were 24 specifically discussed? 25 A Yes.</p> |
| <p style="text-align: right;">Page 275</p> <p>1 abdominal sacrocolpopexy, there have been reports of 2 erosion; correct? 3 A Vaginal erosions, correct. 4 Q And my question to you is whether or not 5 the cause of those erosions is different from the 6 cause of the erosions you see with transvaginal 7 mesh. 8 A As I've already said, the etiology of 9 erosions is not fully understood. Mesh -- bacterial 10 contamination of the mesh is logical in 11 understanding why mesh erosion occurs and why mesh 12 erosion occurs so much more frequently in 13 transvaginal Prolift® mesh implantation than in 14 abdominal mesh implantation. 15 Q And so is the answer that as you sit here 16 today, you don't know whether or not there's a 17 different etiology for mesh erosion associated with 18 abdominal sacrocolpopexy versus the transvaginal 19 inserted mesh? 20 A That is correct. The etiology of mesh 21 erosion is not completely understood. 22 Q We started this discussion when we were 23 talking about your criticisms of the IFU. And I 24 guess my question, Doctor, is if we go through this, 25 are you going to take me through each one of these</p> | <p style="text-align: right;">Page 277</p> <p>1 Q What were those? 2 A I don't remember specifically. It would 3 be in the years between 2005 and 2007, the end of 4 2007, when I was still attending professional 5 meetings. 6 Q Do you remember who presented? 7 A No. 8 Q Do you remember what study was presented? 9 A No. 10 Q Do you remember anything about any 11 discussion at the time? 12 A Discussion, very controversial. Doctors 13 were very gravely concerned that the widespread use 14 of mesh was happening without evidence of safety 15 and, in fact, with strong evidence of grave harm to 16 patients without demonstrated benefit. 17 Q Can you identify for me, Doctor, any 18 doctors who expressed that view? 19 A Dr. Ingrid Nygaard; Dr. Peggy Norton; 20 Dr. Linda Brubaker; Dr. Mary Pat FitzGerald; 21 Dr. Matt Barber; Dr. Scott Smilen, S-M-I-L-E-N; 22 Dr. Robert Porges, P-O-R-G-E-S; Dr. Bob Shull, 23 S-H-U-L-L. Do you want me to keep going? 24 Q All of these doctors expressed a view at 25 this meeting that you attended?</p> |

17 (Pages 274 to 277)

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| <p style="text-align: right;">Page 278</p> <p>1 A I'm reflecting on a number of meetings.</p> <p>2 Q How many meetings did you attend where</p> <p>3 Prolift® was discussed?</p> <p>4 A I can estimate four to six.</p> <p>5 Q And can you tell me what meetings they</p> <p>6 were?</p> <p>7 A I can tell you what meetings they were</p> <p>8 likely to be. The American Urogynecologic Society</p> <p>9 and the Society of Gynecologic Surgeons.</p> <p>10 Q And you would have attended four to six of</p> <p>11 those between 2005 and 2007?</p> <p>12 A They're held annually so that would be</p> <p>13 six, yes. They're separate meetings. Three years,</p> <p>14 two meetings a year, six meetings.</p> <p>15 Q I asked you to identify for me the people</p> <p>16 that expressed concerns. There were also people</p> <p>17 expressing the other side of that, were there not?</p> <p>18 A Yes. Those doctors were largely paid by</p> <p>19 Ethicon.</p> <p>20 Q There were doctors who were not paid by</p> <p>21 Ethicon that were involved in and used mesh, did</p> <p>22 they not?</p> <p>23 A Yes.</p> <p>24 Q Do you remember any of the presentations</p> <p>25 where doctors suggested that the use of transvaginal</p> | <p style="text-align: right;">Page 280</p> <p>1 has been restricted to abdominal use.</p> <p>2 MS. JONES: Move to strike as</p> <p>3 nonresponsive.</p> <p>4 BY MS. JONES:</p> <p>5 Q Doctor, my question was: Do you know how</p> <p>6 many fellowship programs continue to train fellows</p> <p>7 on the use of transvaginal mesh to treat prolapse?</p> <p>8 A No, I don't.</p> <p>9 Excuse me. I'd like to take two minutes</p> <p>10 to go to the restroom.</p> <p>11 MS. JONES: Please.</p> <p>12 (Short recess.)</p> <p>13 BY MS. JONES:</p> <p>14 Q Doctor, I'm going to talk about Ms. Gross</p> <p>15 for a second. So until and unless I tell you</p> <p>16 something else, that's who we're going to be talking</p> <p>17 about. Okay?</p> <p>18 A Okay.</p> <p>19 Q As I understand the opinions that have</p> <p>20 been set forth in your report, you believe that she</p> <p>21 experienced left pudendal neuralgia from Prolift®;</p> <p>22 am I correct?</p> <p>23 A Correct.</p> <p>24 Q Partial urinary retention?</p> <p>25 A Correct.</p> |
| <p style="text-align: right;">Page 279</p> <p>1 mesh was appropriately used for prolapse?</p> <p>2 A No, I do not remember specific</p> <p>3 presentations.</p> <p>4 Q Do you remember the names of any doctors</p> <p>5 who presented on that?</p> <p>6 A Not specifically.</p> <p>7 Q Do you remember whether or not you ever</p> <p>8 saw any presentation involving any of the members of</p> <p>9 the TVM group?</p> <p>10 A I don't remember specifically.</p> <p>11 Q Do you know how many academic institutions</p> <p>12 were training surgeons on the use of transvaginal</p> <p>13 mesh?</p> <p>14 A No.</p> <p>15 Q Do you know how many fellowship programs</p> <p>16 trained fellows on the use of transvaginal mesh?</p> <p>17 A No.</p> <p>18 Q Do you know how many fellowship programs</p> <p>19 continue to train fellows or surgeons on the use of</p> <p>20 transvaginal mesh for treatment of prolapse?</p> <p>21 A Well, they can't train on Prolift® because</p> <p>22 it's been pulled off the market and --</p> <p>23 MS. JONES: Move to strike as</p> <p>24 nonresponsive.</p> <p>25 THE WITNESS: -- Gynemesh® PS mesh</p> | <p style="text-align: right;">Page 281</p> <p>1 Q Mesh erosion and exposure?</p> <p>2 A Correct.</p> <p>3 Q Fear, anxiety, and depression?</p> <p>4 A Correct.</p> <p>5 Q And that she is fully disabled?</p> <p>6 A Correct.</p> <p>7 Q Now, did I correctly summarize the</p> <p>8 case-specific opinions that you have with respect to</p> <p>9 Ms. Gross and her injuries?</p> <p>10 A Yes.</p> <p>11 Q I know that you testified yesterday that</p> <p>12 you were initially contacted in this litigation in</p> <p>13 the fall of 2009. When were you first asked to</p> <p>14 review the medical records of Ms. Gross?</p> <p>15 A I don't know specifically.</p> <p>16 Q Can you give me an approximation of when</p> <p>17 you first began to review Ms. Gross' medical</p> <p>18 records?</p> <p>19 A No.</p> <p>20 Q Can you tell me how long you spent</p> <p>21 reviewing Ms. Gross' medical records in preparation</p> <p>22 of that report?</p> <p>23 A No, I can't estimate that.</p> <p>24 MS. JONES: Counsel, I think you told</p> <p>25 me yesterday that you would get a copy of the</p> |

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| <p style="text-align: right;">Page 282</p> <p>1 financial disclosure.</p> <p>2 MR. SLATER: Oh, yeah. It's sitting</p> <p>3 around the corner. Want me to look for it now?</p> <p>4 MS. JONES: Well, no, but let's get</p> <p>5 it at the break.</p> <p>6 MR. SLATER: Absolutely.</p> <p>7 MS. JONES: Because I would like to</p> <p>8 see it before and mark that.</p> <p>9 MR. SLATER: I have the packet with</p> <p>10 all the experts so I'll give you the whole thing,</p> <p>11 because apparently no one showed it to you.</p> <p>12 MS. JONES: I'm not suggesting --</p> <p>13 MR. SLATER: They're so busy passing</p> <p>14 notes to you they're not giving you our disclosures.</p> <p>15 BY MS. JONES:</p> <p>16 Q Is there any way, Doctor, that you can</p> <p>17 separate out for us the time that you spent</p> <p>18 reviewing and preparing your opinions with respect</p> <p>19 to Ms. Gross?</p> <p>20 A No.</p> <p>21 Q Would the answer be the same with respect</p> <p>22 to Ms. Wicker?</p> <p>23 A Yes.</p> <p>24 Q And I think it's implicit in what I just</p> <p>25 asked you, but it is also correct then that you did</p> | <p style="text-align: right;">Page 284</p> <p>1 A If I understand your question correctly,</p> <p>2 you're asking me to identify something that I don't</p> <p>3 know I've seen. So I don't know how to answer that.</p> <p>4 Q I'm asking the question because, frankly,</p> <p>5 Doctor, what I looked at earlier in terms of the</p> <p>6 materials reviewed didn't necessarily have all the</p> <p>7 Bates numbers and all there so I can't tell exactly</p> <p>8 what you've reviewed from each doctor's files. But</p> <p>9 I do know that you can sometimes review the files</p> <p>10 and it's apparent that you don't have the complete</p> <p>11 file from a given doctor. And that's what I'm</p> <p>12 asking you.</p> <p>13 A I -- it was not obvious to me that chunks</p> <p>14 were missing. I can't say for certainty otherwise.</p> <p>15 Q That's all I'm asking. I'm just asking</p> <p>16 whether or not, to the best of your knowledge, you</p> <p>17 received the complete file from each of the doctors</p> <p>18 whose records you reviewed.</p> <p>19 A Well, again, complete. For example,</p> <p>20 Dr. Likness cared for Mrs. Gross, I don't know, what</p> <p>21 beginning -- beginning at what age, but he was her</p> <p>22 lifetime family physician. So have I reviewed every</p> <p>23 page of her medical records related to Dr. Likness?</p> <p>24 Probably not.</p> <p>25 Q Were you furnished with any summary of the</p> |
| <p style="text-align: right;">Page 283</p> <p>1 not separately invoice Mr. Slater for the</p> <p>2 preparation of your opinions with respect to</p> <p>3 Ms. Gross?</p> <p>4 A Correct.</p> <p>5 Q Or Ms. Wicker?</p> <p>6 A Correct.</p> <p>7 Q To the best of your knowledge, have you</p> <p>8 reviewed the complete medical records of Ms. Gross?</p> <p>9 A Complete as in her whole life?</p> <p>10 Q Well, have you reviewed the complete</p> <p>11 medical records of every doctor whose records you</p> <p>12 have reviewed?</p> <p>13 A Yes, all material provided to me I have</p> <p>14 reviewed.</p> <p>15 Q But that's not really my question. My</p> <p>16 question is: Did you receive excerpts from my</p> <p>17 doctors' files?</p> <p>18 A No. Well --</p> <p>19 Q Here's the question: Sometimes doctors</p> <p>20 only receive copies of the operative reports, for</p> <p>21 example, and not the notes. And that's all I'm</p> <p>22 asking is whether or not you reviewed the complete</p> <p>23 records of the doctors that you have identified in</p> <p>24 the supplemental materials reviewed or whether you</p> <p>25 only received certain portions of those files.</p> | <p style="text-align: right;">Page 285</p> <p>1 medical records?</p> <p>2 A Yes.</p> <p>3 Q Were you furnished with a summary of the</p> <p>4 medical records for both Ms. Wicker and Ms. Gross?</p> <p>5 A Yes.</p> <p>6 Q Do you know who prepared that summary?</p> <p>7 A I don't remember.</p> <p>8 MS. JONES: I know we're going to</p> <p>9 have an argument about this, but I'm going to</p> <p>10 request those summaries.</p> <p>11 MR. SLATER: You can send me a</p> <p>12 letter. I mean, my position is that they were</p> <p>13 provided only to give an idea of what was being</p> <p>14 provided, that Dr. Weber relied on the records, not</p> <p>15 on the summary, so it's work product.</p> <p>16 MS. JONES: Well, I know that's your</p> <p>17 position. We'll take it up later. But I'm going to</p> <p>18 ask for those. And I would ask you --</p> <p>19 MR. SLATER: Are you going to send me</p> <p>20 all your summaries? Are you going to send me all</p> <p>21 the summaries that you did for your experts?</p> <p>22 MS. JONES: I don't send summaries to</p> <p>23 my experts.</p> <p>24 MR. SLATER: Someone does.</p> <p>25 MS. JONES: Not that I know of.</p> |

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| <p style="text-align: right;">Page 286</p> <p>1 BY MS. JONES:</p> <p>2 Q Do you know whether or not you received</p> <p>3 those summaries -- were they in electronic form or</p> <p>4 hard copy?</p> <p>5 A Electronic.</p> <p>6 Q I'm going to ask you, just as I did</p> <p>7 yesterday, if you would maintain those permanently</p> <p>8 up until the time of trial and so forth so that when</p> <p>9 the Court decides what's appropriate for us to get</p> <p>10 or not we will have access to them. Okay?</p> <p>11 A Yes.</p> <p>12 Q Do you know any of the treating physicians</p> <p>13 for Ms. Gross?</p> <p>14 A No.</p> <p>15 Q Are you familiar with Dr. Antolak?</p> <p>16 A Antolak?</p> <p>17 Q Uh-huh.</p> <p>18 A I don't know how to say his name either.</p> <p>19 I'm familiar with him now, of course.</p> <p>20 Q When you say you're familiar with him now,</p> <p>21 in what sense are you familiar with him now?</p> <p>22 A In the course of being a treating</p> <p>23 physician for Mrs. Gross.</p> <p>24 Q Have you reviewed his deposition?</p> <p>25 A Honestly, I need my list of materials</p> | <p style="text-align: right;">Page 288</p> <p>1 Q Yes.</p> <p>2 A Yes.</p> <p>3 Q Did you review summaries of the</p> <p>4 depositions?</p> <p>5 A In some cases, yes.</p> <p>6 Q Were you furnished summaries of all of the</p> <p>7 depositions?</p> <p>8 A No.</p> <p>9 Q Can you tell me what summaries you</p> <p>10 reviewed of the depositions?</p> <p>11 A Dr. Benson. That's the only one I can</p> <p>12 remember.</p> <p>13 Q I asked you, Doctor, when you had reviewed</p> <p>14 the information that relates to Ms. Gross. You said</p> <p>15 you couldn't remember. Did you actually look at it</p> <p>16 during this year, 2012?</p> <p>17 A Yes.</p> <p>18 Q Had you looked at any portion of those</p> <p>19 records before?</p> <p>20 A Yes.</p> <p>21 Q Do you remember whether or not you looked</p> <p>22 at them before the fall of 2011?</p> <p>23 A I don't remember.</p> <p>24 Q Did you receive summaries of any of the</p> <p>25 depositions of the Ethicon witnesses?</p> |
| <p style="text-align: right;">Page 287</p> <p>1 reviewed to know for sure.</p> <p>2 Q I will represent to you I did not see it</p> <p>3 listed on your materials reviewed so I'm --</p> <p>4 MR. SLATER: Wait. You're looking at</p> <p>5 the wrong list then.</p> <p>6 MS. JONES: Well, I may be.</p> <p>7 MR. SLATER: There's been updated</p> <p>8 lists. I'm just telling you. He's definitely</p> <p>9 listed. I'll find out during lunch.</p> <p>10 MS. JONES: I mean, let's do this</p> <p>11 during lunch: Can we get what you believe is the</p> <p>12 complete list --</p> <p>13 MR. SLATER: Absolutely.</p> <p>14 MS. JONES: -- of everything at</p> <p>15 lunch?</p> <p>16 MR. SLATER: Yes.</p> <p>17 MS. JONES: Just check, because I</p> <p>18 will represent to you that what I was looking at did</p> <p>19 not have that deposition transcript listed.</p> <p>20 BY MS. JONES:</p> <p>21 Q Did you receive the entire deposition</p> <p>22 transcripts for the doctors and witnesses that you</p> <p>23 reviewed?</p> <p>24 A Do you mean when I received deposition</p> <p>25 transcripts, were they complete?</p> | <p style="text-align: right;">Page 289</p> <p>1 A Yes.</p> <p>2 Q Tell me which witnesses you received</p> <p>3 summaries on.</p> <p>4 A To the best of my recollection, Dr. Piet</p> <p>5 Hinoul. That's all I can remember.</p> <p>6 Q Did you receive complete deposition</p> <p>7 transcripts on the Ethicon witnesses?</p> <p>8 A Yes.</p> <p>9 Q Did you receive all of the exhibits to</p> <p>10 those depositions?</p> <p>11 A No.</p> <p>12 Q Have you requested any other Ethicon</p> <p>13 documents for review that you've not yet seen?</p> <p>14 A No.</p> <p>15 Q Before you reviewed the deposition of</p> <p>16 Dr. Antolak, were you familiar with his reputation</p> <p>17 as a specialist on pudendal neuralgia?</p> <p>18 A No. Well, let me just say in reviewing</p> <p>19 the records of Mrs. Gross, she had seen Dr. Antolak.</p> <p>20 So at that point I became aware of his specialty in</p> <p>21 pudendal neuralgia. So that would be at some time</p> <p>22 before his deposition.</p> <p>23 Q Did you do any investigation or research</p> <p>24 on Dr. Antolak?</p> <p>25 A I believe I searched his name on PubMed,</p> |

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| <p style="text-align: right;">Page 290</p> <p>1 the medical literature.</p> <p>2 Q And did you do any searches on any of</p> <p>3 Ms. Gross' other doctors?</p> <p>4 A Yes; Dr. Hibner, again from the medical</p> <p>5 literature.</p> <p>6 Q And did you pull and review any of the</p> <p>7 medical articles written by either Dr. Hibner or</p> <p>8 Dr. Antolak?</p> <p>9 A Yes.</p> <p>10 Q And are the articles that you pulled and</p> <p>11 reviewed identified on the list of materials</p> <p>12 reviewed?</p> <p>13 A Yes, if there were articles.</p> <p>14 Q Let me ask you this: Do you recall</p> <p>15 reading articles authored by either of those two</p> <p>16 doctors?</p> <p>17 A I can't be sure. If I read them, they're</p> <p>18 on the list.</p> <p>19 Q Let me ask you, have you reviewed any</p> <p>20 materials from the Social Security Administration on</p> <p>21 Ms. Gross?</p> <p>22 A No.</p> <p>23 Q You identified three experts' reports that</p> <p>24 you had reviewed before preparing your opinions, and</p> <p>25 those were those of Dr. Serrato, Dr. Welch, and</p> | <p style="text-align: right;">Page 292</p> <p>1 A I cannot say for sure.</p> <p>2 Q Are the photomicrographs specifically</p> <p>3 identified on the list of materials reviewed</p> <p>4 according to which institution they would have come</p> <p>5 from?</p> <p>6 A No.</p> <p>7 Q Are they identified in any way?</p> <p>8 A I believe they're identified by her name,</p> <p>9 Linda Gross, and by a number.</p> <p>10 Q And what do you think that number refers</p> <p>11 to?</p> <p>12 A I don't know.</p> <p>13 Q You don't know whether they're exhibits to</p> <p>14 the deposition or whether they're something from the</p> <p>15 medical records?</p> <p>16 A They may have been used as exhibits. They</p> <p>17 are not labeled as exhibits.</p> <p>18 MS. JONES: Counsel, I'm going to ask</p> <p>19 specifically that those photomicrographs be</p> <p>20 produced.</p> <p>21 MR. SLATER: You have them already.</p> <p>22 MS. JONES: I just want to know which</p> <p>23 ones they are so that we --</p> <p>24 MR. SLATER: You have them all. She</p> <p>25 was given everything I produced to you. When</p> |
| <p style="text-align: right;">Page 291</p> <p>1 Dr. Provder; is that correct?</p> <p>2 A Mr. Provder, yes.</p> <p>3 Q And did you rely upon the report of</p> <p>4 Dr. Serrato in formulating your opinions?</p> <p>5 A Yes.</p> <p>6 Q Did you review the ultrasounds that Dr.</p> <p>7 Serrato performed?</p> <p>8 A No.</p> <p>9 Q Have you ever seen any ultrasounds on</p> <p>10 Ms. Gross?</p> <p>11 A No.</p> <p>12 Q Have you seen any radiology at all with</p> <p>13 respect to Ms. Gross?</p> <p>14 A No.</p> <p>15 Q Have you seen any pathology with respect</p> <p>16 to Ms. Gross?</p> <p>17 A Yes.</p> <p>18 Q Tell me what you've seen.</p> <p>19 A I have seen histology slides,</p> <p>20 photomicrographs of mesh and tissue.</p> <p>21 Q Have you seen the actual slides or just</p> <p>22 the photomicrographs?</p> <p>23 A Just the photomicrographs.</p> <p>24 Q And do you know who prepared those</p> <p>25 photomicrographs?</p> | <p style="text-align: right;">Page 293</p> <p>1 Dr. Welch's report was produced, we gave you all of</p> <p>2 the photomicrographs of every single slide he looked</p> <p>3 at and those were provided to Dr. Weber.</p> <p>4 MS. JONES: That's all I'm trying to</p> <p>5 figure out is what photomicrographs Dr. Weber has</p> <p>6 actually seen because she can't identify them for</p> <p>7 me.</p> <p>8 MR. SLATER: Dr. Welch had those</p> <p>9 prepared in his offices at Harvard and then they</p> <p>10 were provided to me and I bounced them to Dr. Weber.</p> <p>11 And she had those plus the report to look at. We</p> <p>12 produced to you all the photomicrographs so you have</p> <p>13 everything she saw.</p> <p>14 MS. JONES: That's fine. I just want</p> <p>15 to know what it is that she saw. That's all I'm</p> <p>16 asking.</p> <p>17 MR. SLATER: I've produced it to you</p> <p>18 already. I mean, I can't tell you which specific</p> <p>19 slides. You have them. You can put them up on a</p> <p>20 screen and say did you see this. I don't know that</p> <p>21 she'd be able to say I saw this slide, that slide.</p> <p>22 She had them all. Everything that I produced to you</p> <p>23 was given to her electronically. We sent it to her.</p> <p>24 And we produced it to you on a disk. You have all</p> <p>25 of them.</p> |

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| <p style="text-align: right;">Page 294</p> <p>1 And the numbers, I don't have the 2 list of materials reviewed, but I assume the list of 3 numbers is the numbers from the institutions where 4 they identify the path slides. I mean, they have 5 section numbers, whatever you call them. 6 BY MS. JONES: 7 Q So that what we're clear on, Doctor, is 8 that the photomicrographs you have gotten are the 9 ones from Dr. Welch? 10 MR. SLATER: Yes. 11 MS. JONES: Not from any other 12 institution, not prepared by any other institution? 13 That was my question. 14 MR. SLATER: To my knowledge, there 15 are no other photomicrographs. 16 MS. JONES: That's the reason I'm 17 asking the question. 18 MR. SLATER: Do you have any that I 19 don't know of? Want to throw all our chips into the 20 middle of the table? No, I'm not aware of any. In 21 fact, I just e-mailed my partner to find out if the 22 defense experts prepared any photomicrographs on the 23 slides they looked at because I don't think we were 24 produced any. So I actually just e-mailed Dave 25 Mazie to find out because I don't think we got any</p> | <p style="text-align: right;">Page 296</p> <p>1 A Can you help me understand what you mean 2 by a diagnostic conclusion? 3 Q For what purpose did you look at the 4 photomicrographs? 5 A To correlate them with the findings of 6 Dr. Welch. 7 Q Of Dr. Welch? 8 A Dr. Welch. 9 THE WITNESS: Did I speak correctly? 10 MR. SLATER: Yeah. 11 BY MS. JONES: 12 Q Prior to receiving the report of Dr. Welch 13 and the photomicrographs, had you looked at any of 14 the pathology for Ms. Gross? 15 A No. 16 Q Had you expressed any opinion with respect 17 to the pathology for Mrs. Gross prior to seeing 18 Dr. Welch's report? 19 A No. 20 Q Is it a fair assumption that you rely upon 21 Dr. Welch for any of your opinions with respect to 22 the pathology? 23 A Yes. 24 Q So that you don't have independent 25 opinions on the pathology beyond what Dr. Welch</p> |
| <p style="text-align: right;">Page 295</p> <p>1 from the defense. They may not have prepared any. 2 I'm assuming they did; otherwise, there's no way to 3 show them to the jury. 4 MS. JONES: I think we're clear on 5 this now. That's all I want to know is what it is 6 the doctor has seen. 7 MR. SLATER: The photomicrographs -- 8 what happened was recuts were provided to Dr. Welch. 9 He looked at them. He had micrographs prepared. I 10 don't know the process. It's some sophisticated 11 camera on a microscope or something probably. I can 12 barely work my own camera. And then whatever he 13 prepared was sent to us electronically, provided on 14 disks, we copied the disks, we provided that all to 15 you. And whatever we were provided by Dr. Welch, we 16 bounced it to Dr. Weber so she had what we had. 17 BY MS. JONES: 18 Q And you have not seen anything other than 19 the photomicrographs -- 20 A Correct. 21 Q -- with respect to the pathology? 22 And, Doctor, have you attempted, based 23 upon those photomicrographs, to look at it and come 24 to any diagnostic conclusions based upon review of 25 those photomicrographs?</p> | <p style="text-align: right;">Page 297</p> <p>1 reported? 2 A Correct. 3 Q And is the same true with respect to 4 Dr. Serrato? 5 A With respect to the ultrasound findings 6 you mean? 7 Q Yes. 8 A Yes, correct. 9 Q And is there anything in Mr. Provder's 10 report upon which you rely in forming your opinions? 11 A Yes. 12 Q What is that? 13 A On his assessment of her level of 14 disability and inability to return to her 15 profession. 16 Q And you understand that she is a nurse by 17 profession? 18 A I understand that. 19 Q Would you agree that pudendal neuralgia is 20 a pain syndrome? 21 A Yes. 22 Q Can you tell me what the symptoms of 23 pudendal neuralgia are? 24 A There are several characteristic symptoms 25 that will vary from patient to patient. Pain in the</p> |

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| <p style="text-align: right;">Page 298</p> <p>1 distribution of the pudendal nerve, pain that's 2 worsened with sitting, pain that may be relieved by 3 standing or lying down. That's all. 4 Q Are you familiar with a burning sensation 5 being associated with pudendal neuralgia? 6 A Neuropathic pain is often described by the 7 patient as having a burning character. 8 Q How about numbness? 9 A Numbness is not strictly a symptom of 10 pain, a characteristic -- a description of the 11 patient's pain experience. 12 Q Well, maybe I wasn't clear. I was asking 13 really about symptoms of the pudendal neuralgia. 14 A No, I don't think numbness would be a 15 characteristic typical of pudendal neuralgia. 16 Q Are you familiar with feelings of a lump 17 or foreign body in the vagina or rectum associated 18 with pudendal neuralgia? 19 A It can be. 20 Q How about abnormal temperature sensations 21 like flushing? 22 A As a response to the pain itself. Maybe 23 you can clarify for me. Are you talking about the 24 symptoms specific to pudendal neuralgia or the 25 symptoms the patient may experience as a result of</p> | <p style="text-align: right;">Page 300</p> <p>1 Q How about painful intercourse? 2 A Again, as a result of the distribution of 3 the pudendal nerve in the vaginal area, yes, pain. 4 Q How about musculoskeletal pain in other 5 parts of the pelvis? 6 A You mean other parts than the distribution 7 of the pudendal nerve? 8 Q Right, right. 9 A Okay. So that answer would be no. 10 Q Would be? 11 A No. 12 Q So that I understand that last answer, you 13 don't think that pudendal neuralgia is or can be 14 accompanied by musculoskeletal pain in other parts 15 of the pelvis? 16 A Well, let me see if I can clarify that. 17 The pain of pudendal neuralgia can lead to pelvic 18 muscle spasm. And pelvic muscle spasm can occur on 19 both sides of the pelvis, the side on which the 20 pudendal neuralgia exists and also on the other 21 side. 22 Q Can you see pudendal neuralgia and pelvic 23 floor dysfunction together? 24 A Well, what do you mean by "pelvic floor 25 dysfunction"?</p> |
| <p style="text-align: right;">Page 299</p> <p>1 the pain of the pudendal neuralgia? 2 Q I'm really just talking about symptoms 3 that have been reported in association with pudendal 4 neuralgia. 5 A Okay. So, no, I would say apart from an 6 association or an event associated with the 7 patient's pain, an abnormal flushing feeling would 8 not be a typical symptom of pudendal neuralgia. 9 Q How about constipation? 10 A Again, not specific as a typical symptom 11 confined to pudendal neuralgia itself. 12 Q How about pain or straining with bowel 13 movements? 14 A Well, that is in the distribution of the 15 pudendal nerve so that would be consistent, not 16 straining per se but pain. 17 Q How about straining or burning with 18 urination? 19 A It's possible, again, with the 20 distribution of the pudendal nerve. 21 Q How about a sense that the bladder is not 22 empty or never empty? 23 A Again, possible based on the distribution. 24 Q How about low back pain? 25 A No, I don't think that would be typical.</p> | <p style="text-align: right;">Page 301</p> <p>1 Q Well, I said that because I was listening 2 to you talking about pelvic spasms. If you had some 3 dysfunction of the pelvic floor musculature, could 4 you see that in conjunction with pudendal neuralgia? 5 A Yes. 6 Q And in the course of your practice, 7 Doctor, did you regularly treat pudendal neuralgia? 8 A No. 9 Q If somebody came in with what you 10 diagnosed as pudendal neuralgia, would you refer 11 them out? 12 A I would evaluate the patient from a 13 urogynecologic perspective and offer the patient 14 what I felt was appropriate on that basis. If I 15 felt that there were contributors or possibly the 16 entire etiology outside of my scope of 17 urogynecology, then I would either -- if I felt 18 there was a contribution, I would refer her and work 19 in conjunction with the referring -- with the doctor 20 to which I would refer her. If I felt it was 21 entirely outside the scope of urogynecology, then I 22 would simply refer her. 23 Q What is your understanding are the causes 24 of pudendal neuralgia? 25 A Well, there are several: Trauma; in some</p> |

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| <p style="text-align: right;">Page 302</p> <p>1 people situations where they are sitting 2 specifically, for example, on a bicycle or a 3 motorcycle, whether it's the pressure of them 4 sitting on that position or the vibration, say, of a 5 motorcycle engine, there is that association; 6 surgery, of course. 7 Q We talked earlier already about different 8 forms of prolapse surgery that might be associated 9 with pudendal neuralgia, but has hysterectomy been 10 associated with pudendal neuralgia? 11 A No, hysterectomy by itself, no. 12 Q What about childbirth or difficult 13 deliveries? 14 A Yes, that would be possible. 15 Q Infections in the pelvic floor? 16 A Infections in the pelvic floor? You 17 mean -- 18 Q Or infections in the pelvis. 19 A In the pelvis. No, I have not heard that 20 as being a cause of pudendal neuralgia. 21 Q And when a patient presented to you with 22 symptoms that you thought might indicate pudendal 23 neuralgia, how would you go about making that 24 diagnosis? 25 A I would obtain her history, see if there</p> | <p style="text-align: right;">Page 304</p> <p>1 experiences pain relief. It's diagnostic in the 2 sense that if she experiences pain relief, that's a 3 very strong indication, what many doctors feel is 4 the strongest indication, that you are, in fact, 5 dealing with pudendal neuralgia; and then 6 therapeutic obviously in the sense that if her pain 7 is relieved, she feels better. 8 Q And did you actually when you were 9 practicing perform pudendal nerve blocks? 10 A Not in my -- during my residency, yes; not 11 since then. 12 Q During your residency between '88 and '92? 13 A Correct. 14 Q Would that have been the last time that 15 you've treated pudendal neuralgia? 16 A Yes. 17 Q Other than the nerve block, is there any 18 other type of treatment that you would have 19 prescribed for pudendal neuralgia that you can 20 remember? 21 A I would not. At that point I would 22 involve another physician with expertise. 23 Q In the case of Ms. Gross, is it your 24 opinion that the surgery that she had for prolapse 25 caused the pudendal neuralgia or is it the use of</p> |
| <p style="text-align: right;">Page 303</p> <p>1 were any identifiable factors that may have caused 2 or contributed to this situation. I would ask her 3 for a very detailed explanation or description of 4 her pain: The location; any factors that relieved 5 it or exacerbated it; the nature of the pain, any 6 describing words that she could give me; the 7 duration; a complete history related to the pain; 8 and then any other points of her history that could 9 potentially be relevant; and then an examination in 10 the pelvic area to map the distribution of her pain 11 to see if it was consistent with the distribution of 12 the pudendal nerve; and then an external examination 13 to see if that reproduced her pain or exacerbated 14 it; and then an internal examination to see if there 15 was any other information that I could gather as to 16 the location or the reproducibility of the pain with 17 examination. 18 Q And what type of treatment would you 19 prescribe? 20 A Again, this is where -- once I had a 21 better understanding of the possible cause where I 22 would be likely to involve a second physician. A 23 pudendal -- a nerve block -- I could administer a 24 pudendal nerve block in the office. And that has 25 both a diagnostic and a therapeutic effect if she</p> | <p style="text-align: right;">Page 305</p> <p>1 mesh that caused the pudendal neuralgia? 2 A I think it is most likely that the 3 pudendal neuralgia was caused by the proximity of 4 the mesh itself. I can't rule out the possibility 5 of a contributing factor that occurred during the 6 surgery. 7 Q And can you tell me why you think it is 8 most likely to be the proximity of the mesh 9 itself? The proximity of the mesh to the nerve? 10 A Correct. 11 Q And why do you reach that conclusion? 12 A I am not sure I understand your question. 13 Why -- 14 Q Why is it that you believe that it's the 15 proximity of the mesh to the nerve that's caused the 16 neuralgia as opposed to the surgery itself? 17 A I think if Mrs. Gross had had a direct 18 very traumatic injury, such as the trocar passage 19 through the pudendal nerve, that would have been 20 immediately evident when she was woken from 21 anesthesia. I think it's possible that she had a 22 less severe injury due to trocar passage. As I 23 said, I can't rule that out. 24 After surgery then it's the mesh 25 placement, the inflammatory and foreign body</p> |

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| <p style="text-align: right;">Page 306</p> <p>1 reaction that it causes, the fibrosis and scarring 2 in very close proximity to the nerve, if not on the 3 nerve, that led to her pudendal neuralgia. 4 Q And did you review the medical records of 5 Ms. Gross to determine whether or not she had 6 experienced any signs or symptoms before the surgery 7 that might be indicative of pudendal neuralgia? 8 A Yes. 9 Q Did you find any? 10 A No. 11 Q So when you went back and looked at the 12 records, you did not find that she had experienced 13 any symptoms that had been associated with pudendal 14 neuralgia? 15 MR. SLATER: You're talking about 16 prior to the surgery? 17 MS. JONES: Prior to the surgery. 18 THE WITNESS: I didn't find any 19 evidence that she had symptoms of pudendal neuralgia 20 before the Prolift® surgery. 21 BY MS. JONES: 22 Q Did you find that Ms. Gross had a prior 23 history of stress urinary incontinence? 24 A Yes. 25 Q Of obstructed defecation?</p> | <p style="text-align: right;">Page 308</p> <p>1 any way? 2 A His surgical technique was not incorrect 3 based on his operative report. The trocar passages 4 themselves introduce an unreasonable degree of risk 5 of nerve damage specifically along with other types 6 of damage in the Prolift® procedure. 7 Q My understanding, though, from what you 8 testified earlier, and I'm just asking, is that if 9 Ms. Gross had experienced nerve damage as a result 10 of the use of the trocars, you would have expected 11 to have seen that immediately? 12 A Direct severely traumatic as in driving 13 the trocar right through the nerve. Also, the 14 pudendal nerve at various places, because everyone's 15 anatomy is different, branches into its three 16 terminal branches. It's possible that one of the 17 smaller branches was directly injured. As I said, I 18 cannot rule it out. 19 Q I understand that you can't rule it out. 20 But am I correct that even though you say you can't 21 rule it out, your belief and position as you sit 22 here today is that the nerve damage was not as 23 likely due to the trocar as it was to the placement 24 of the mesh? 25 A Correct.</p> |
| <p style="text-align: right;">Page 307</p> <p>1 A Those were her symptoms, yes. 2 Q And had a rectocele? 3 A Yes. 4 Q Ms. Gross had also had several 5 pregnancies, had she not? 6 A Three. 7 Q There were some difficult deliveries? 8 A What do you mean by "difficult"? 9 Q Well, she had a fourth-degree vaginal 10 tear, didn't she? 11 A Actually in reading the doctor's delivery 12 note, he cut the fourth-degree to make room for the 13 delivery of the fetus. 14 Q Had she had any pelvic spasms of which 15 you're aware? 16 A Pelvic muscle spasm? 17 Q Uh-huh. 18 A No, not to my knowledge. 19 Q So do I understand your opinion, Doctor, 20 to be that Dr. Benson's use of trocars in the 21 Prolift® surgery did not likely cause the pudendal 22 nerve injury? 23 A I can't rule it out. 24 Q Do you have any opinion as to whether or 25 not Dr. Benson's surgical technique was incorrect in</p> | <p style="text-align: right;">Page 309</p> <p>1 Is this a good time for a break? 2 (Discussion off the record.) 3 MS. JONES: Can we go ahead until we 4 get lunch? 5 THE WITNESS: Yes. 6 BY MS. JONES: 7 Q Are you aware, Doctor, of any place in the 8 medical records where there's any mention or 9 discussion of pudendal nerve damage prior to August 10 of 2007? 11 A Can I look at my report, please? 12 Q Yes. 13 MR. SLATER: Yeah, sure. I have it 14 on the floor here. 15 BY MS. JONES: 16 Q Doctor, I'll tell you where I think it is. 17 I picked that up on Page 6 of your report. And my 18 note says the first mention of pudendal nerve damage 19 as a cause of the symptoms was recorded on 20 August 29th, 2007. 21 A Okay. And that's on Page 6? 22 Q I have it marked on Page 6. That's what I 23 took my notes from. 24 THE WITNESS: Can I ask you a 25 question? Should we step out or can I just ask you?</p> |

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| <p style="text-align: right;">Page 310</p> <p>1 MR. SLATER: No. Don't ask me 2 anything. I mean, if there's something missing from 3 this notebook, then I have to just get someone to 4 bring it in. The page number may just be a typo or 5 something on her outline. 6 MS. JONES: It may be. I promise 7 this is not a trick. I have my notes. 8 THE WITNESS: Yeah, I just -- I don't 9 see what you're saying. 10 BY MS. JONES: 11 Q I don't see it on Page 6 either. I've 12 obviously got a typo on it. 13 MR. SLATER: Off the record. 14 (Discussion off the record.) 15 BY MS. JONES: 16 Q All right. Doctor, while we were off the 17 record, it is on Page 5 that you note in your report 18 that the first mention of pudendal nerve damage as a 19 cause of Ms. Gross' symptoms was on August 29, 2007; 20 correct? 21 A Correct. 22 Q And you mentioned that you had treated 23 pudendal neuralgia in your residency. Was it in 24 medical school or in the residency that you were 25 taught the distribution of the pudendal nerve?</p> | <p style="text-align: right;">Page 312</p> <p>1 think I caught the last of what you said about how 2 it could -- I know we talked about the approach, but 3 tell me how it entraps the nerve. 4 A So the superior surface of the 5 sacrospinous ligament, the ischial spine, and the 6 pudendal nerve are all in very close proximity. The 7 surgeon in passing a suture through the superior 8 aspect of the sacrospinous ligament may 9 inadvertently include the pudendal nerve in that 10 suture, entrapping it. It's called pudendal nerve 11 entrapment. 12 Q And it's that type of entrapment that's 13 generally the cause of pudendal nerve neuralgia in 14 the sacrospinal ligament fixation surgery? 15 A Correct. 16 Q The surgery that Ms. Gross had on the 17 pudendal nerve was in June of 2009; correct? 18 A Yes. 19 Q And it was performed by Dr. Hibner? 20 A Yes. 21 Q At the time that Dr. Hibner performed that 22 surgery, he did not find the presence of mesh, did 23 he? 24 A There's conflicting information on that 25 point. The operative note which he dictated</p> |
| <p style="text-align: right;">Page 311</p> <p>1 A Both. 2 Q And were you taught to do the pudendal 3 nerve block in your residency or in medical school? 4 A I certainly learned it in my residency. I 5 don't remember if I learned it in medical school 6 also. 7 Q You testified earlier that pudendal nerve 8 damage can be the result of the sacrospinal ligament 9 fixation? 10 A Correct. 11 Q And my question is, how is it caused by 12 that surgery? 13 A Typically it's an entrapment where the 14 suture -- in a sacrospinous ligament fixation, the 15 surgeon is approaching the sacrospinous ligament 16 from its superior aspect. And the pudendal nerve in 17 relation to the ischial spine and the sacrospinous 18 ligament is in very close proximity in such a way 19 that a suture can be passed into the substance of 20 the sacrospinous ligament and entrap the pudendal 21 nerve. 22 Q Would you say that again, please? 23 A Do you want me to rephrase it or -- 24 Q No, no, no. I just -- I think my mind 25 went in and out just for a second. I just don't</p> | <p style="text-align: right;">Page 313</p> <p>1 immediately after performing the operation has a 2 description of mesh attached directly to the 3 pudendal nerve. Under testimony Dr. Hibner 4 testified that he did not believe it was mesh; if it 5 were mesh, he would have sent it for pathology, and 6 he did not send it for pathology and he believed it 7 was scar tissue. 8 Now, in terms of causing Mrs. Gross' 9 pudendal neuralgia, whether it was mesh or not, 10 according to Dr. Hibner's conflicting information, 11 she had pudendal neuralgia on the basis of the mesh 12 implantation near or -- adjacent to or touching the 13 pudendal nerve in such a way that the inflammatory 14 body reaction, the scarring, the fibrosis from the 15 Prolift® mesh implantation was responsible for her 16 pudendal neuralgia. 17 Q Have you seen any pathology that shows 18 that mesh is in any of the scar tissue around the 19 pudendal nerve? 20 A As I understood from Dr. Hibner's 21 testimony, he did not send that specimen for 22 pathology. 23 Q And you've not seen any pathology from any 24 other surgery or any other findings that mesh was 25 actually removed from the pudendal nerve?</p> |

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| <p style="text-align: right;">Page 314</p> <p>1 A Again, to my understanding from 2 Dr. Hibner's testimony, that wasn't sent for 3 pathology. You wouldn't take -- even if he had 4 taken mesh off the pudendal nerve, unless he excised 5 the pudendal nerve or a part of it, that would not 6 show up in the pathology specimen. 7 Q You wouldn't send an encased mesh to 8 pathology? 9 A According to my understanding of the 10 operative note, mesh or scar -- mesh, that's in the 11 operative note, Dr. Hibner's testimony, scar tissue 12 was found attached to the pudendal nerve. The goal 13 of the operation, of course, is to leave the 14 pudendal nerve intact. If you excise a portion of 15 the pudendal nerve and send it to pathology, the 16 patient is obviously going to suffer from that 17 excision. 18 Q My question was really a little different, 19 Doctor. If you as a surgeon excised tissue in which 20 mesh was encased, would you have sent that to 21 pathology? 22 A Yes. 23 Q And would you think that that would be the 24 standard of care for a surgeon to send that material 25 to pathology?</p> | <p style="text-align: right;">Page 316</p> <p>1 Dr. Benson performed a surgery to excise the 2 Prolift® vaginal mesh; correct? 3 A To my understanding, he was concentrating 4 on the anterior portion of the Prolift® mesh at that 5 surgery. 6 Q And subsequently Ms. Gross had other 7 portions of the Prolift® removed; correct? 8 A Yes. 9 Q Did Ms. Gross suffer from interstitial 10 cystitis? 11 A In my opinion, no. 12 Q What's that opinion based upon? 13 A That opinion is based upon the -- my 14 understanding of the course of interstitial cystitis 15 and how that did not match up with Linda Gross' 16 course. 17 Q Tell me what you understand the typical 18 course of interstitial cystitis to be. 19 A Well, first I'll explain interstitial 20 cystitis is a collection of symptoms. In its severe 21 form that leads to cystoscopic findings, it is a 22 chronic disease or condition with symptoms of 23 urgency, frequency, and bladder pain that occur over 24 the course of months and years. 25 Mrs. Gross didn't have a diagnosis of</p> |
| <p style="text-align: right;">Page 315</p> <p>1 A I was taught to send all material to 2 pathology. You take it out of the patient, you send 3 it to pathology. I can't really speak to what every 4 other surgeon does. 5 Q That's what you would have taught your 6 residents and fellows when you were involved in 7 academic medicine? 8 A Correct. 9 Q I take it that it's your position that 10 Ms. Gross would not have had pudendal nerve 11 neuralgia but for the use of Prolift®? 12 A Correct. 13 Q Have you seen any medical literature 14 specifically that relates to Prolift® and pudendal 15 nerve involvement? 16 A No. 17 Q Mrs. Gross had mesh removed and the 18 Prolift® removed in early 2007, did she not? 19 MR. SLATER: Objection to the form. 20 You can answer. 21 THE WITNESS: The date again, please? 22 BY MS. JONES: 23 Q I confess to you, Doctor, I'm looking for 24 the exact date. I don't have it in my notes. 25 In December, December 14 of 2006,</p> | <p style="text-align: right;">Page 317</p> <p>1 interstitial cystitis before she had the Prolift® 2 placed. I believe it was approximately two months 3 after the Prolift® procedure Dr. Benson performed a 4 cystoscopy and described findings that he attributed 5 to the possibility of interstitial cystitis. On 6 subsequent cystoscopies those findings were not 7 repeated. 8 So on that basis she didn't have it 9 before, she had one cystoscopy two months after the 10 surgery at a time when she was experiencing urinary 11 tract infections, retention -- and urinary 12 retention, and the cystoscopic findings were never 13 seen again on subsequent cystoscopies. 14 Q You told us yesterday that you had spoken 15 with one of the other plaintiffs' experts with 16 respect to interstitial cystitis; am I correct? 17 A Yes. 18 Q And who was that? 19 A That was Dr. Elliott. 20 Q And did you speak with Dr. Elliott 21 specifically about the diagnosis of interstitial 22 cystitis in Ms. Gross? 23 A I can't remember. 24 Q Does Dr. Elliott, if you know, have a more 25 extensive background in the treatment of</p> |

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| <p style="text-align: right;">Page 318</p> <p>1 interstitial cystitis in women than you do?</p> <p>2 A Yes, I would presume so.</p> <p>3 Q In your practice, Doctor, did you</p> <p>4 regularly treat women with interstitial cystitis?</p> <p>5 A No.</p> <p>6 Q Do you know how many women you actually</p> <p>7 treated with interstitial cystitis?</p> <p>8 A No.</p> <p>9 Q After you completed your residency, did</p> <p>10 you treat anyone with interstitial cystitis?</p> <p>11 A I'm sure I saw patients with a history of</p> <p>12 stable interstitial cystitis. I did not treat</p> <p>13 patients with bladder distillation or</p> <p>14 hydrodistention or any other form of that kind of</p> <p>15 treatment.</p> <p>16 Q And would you regularly refer people with</p> <p>17 those conditions to urologists?</p> <p>18 A Yes.</p> <p>19 Q Are there sources of inflammation in the</p> <p>20 pelvic floor other than mesh, for example?</p> <p>21 A In the pelvic floor?</p> <p>22 Q Uh-huh.</p> <p>23 A The pelvic musculature? Source of</p> <p>24 inflammation. Certainly, muscles can be inflamed</p> <p>25 for reasons other than mesh.</p> | <p style="text-align: right;">Page 320</p> <p>1 causative or contributing factors that could be</p> <p>2 addressed by behavioral or lifestyle changes, if</p> <p>3 something was triggering the pain specifically. If</p> <p>4 there weren't any known triggers that I could</p> <p>5 address, then it's empiric treatment for muscle</p> <p>6 relaxation. I would start with physical therapy. I</p> <p>7 would add pharmacologic therapy if needed.</p> <p>8 Q And would you follow the same process with</p> <p>9 respect to myofascial pain?</p> <p>10 A Myofascial pain is -- myofascial pain is</p> <p>11 used synonymously with pelvic muscle spasm.</p> <p>12 Q With muscle spasms?</p> <p>13 A Pelvic muscle spasm, hypertonicity,</p> <p>14 levator myalgia. There isn't one name for this</p> <p>15 condition.</p> <p>16 Q I understand. When you said synonymously,</p> <p>17 it threw me off a little bit, because I thought you</p> <p>18 said that muscle spasms were synonymous with</p> <p>19 myofascial pain. Maybe I misunderstood.</p> <p>20 A Well, myofascial pain is not specific.</p> <p>21 That could be any muscles in the body. So are you</p> <p>22 talking about pelvic myofascial pain?</p> <p>23 Q I am.</p> <p>24 A Okay. So then it's possible you could</p> <p>25 have pelvic muscle spasm without pain. But if you</p> |
| <p style="text-align: right;">Page 319</p> <p>1 Q For example, could you have inflammation</p> <p>2 associated with muscle spasms or tension? And let</p> <p>3 me say muscle spasms or tension in the pelvic floor</p> <p>4 muscles, the musculature.</p> <p>5 A So are you asking whether inflammation is</p> <p>6 the starting point and then it's associated with the</p> <p>7 development of pelvic muscle spasm?</p> <p>8 Q No. I'm asking whether or not muscle</p> <p>9 spasms or tension in the pelvic floor muscles can be</p> <p>10 a source of inflammation, can lead to inflammation.</p> <p>11 MR. SLATER: Are you talking about</p> <p>12 generalized inflammation or any particular</p> <p>13 inflammation?</p> <p>14 MS. JONES: Just inflammation.</p> <p>15 MR. SLATER: Objection.</p> <p>16 You can answer.</p> <p>17 THE WITNESS: Not to my knowledge.</p> <p>18 BY MS. JONES:</p> <p>19 Q During the course of your practice,</p> <p>20 Doctor, did you treat patients with pelvic floor</p> <p>21 muscle pain?</p> <p>22 A Yes.</p> <p>23 Q And what type of treatment did you</p> <p>24 prescribe for those patients?</p> <p>25 A Well, in her history I would look for any</p> | <p style="text-align: right;">Page 321</p> <p>1 have pelvic muscle spasm and pain, that would be</p> <p>2 used interchangeably with pelvic myofascial pain.</p> <p>3 Q Are there other sources of pelvic</p> <p>4 myofascial pain other than muscle spasms?</p> <p>5 A Sure. Anything that can happen to a</p> <p>6 muscle. You can strain it. You can bruise it, I</p> <p>7 suppose. You could -- it could be traumatized in</p> <p>8 some way.</p> <p>9 Q Can stress trigger myofascial pain?</p> <p>10 A Like emotional stress?</p> <p>11 Q Yeah.</p> <p>12 A As opposed to physical stress?</p> <p>13 Q Well, physical stress could obviously</p> <p>14 trigger it; right?</p> <p>15 A Right.</p> <p>16 Q Could emotional stress?</p> <p>17 A Emotional stress. It could certainly</p> <p>18 exacerbate it. It could trigger it if a woman for</p> <p>19 some reason was adding an element of voluntary</p> <p>20 contraction -- muscle tension, of course, anywhere</p> <p>21 is a very common reaction to stress so I don't see</p> <p>22 any reason why it couldn't affect the pelvis.</p> <p>23 Q Is it your opinion, Doctor, that Ms. Gross</p> <p>24 benefited from pelvic physical therapy?</p> <p>25 A After her surgery to treat her pelvic</p> |

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| <p style="text-align: right;">Page 322</p> <p>1 muscle spasm? Is that what you're referring to?</p> <p>2 Q No. You know that she did receive some</p> <p>3 physical therapy and pelvic floor tone and</p> <p>4 relaxation physical therapy, do you not?</p> <p>5 A Yes. So that would be after her surgery</p> <p>6 to treat her pelvic muscle spasm; no?</p> <p>7 Q And it was recommended that she</p> <p>8 participate in a pain management program, wasn't it?</p> <p>9 A That was offered to her as an option.</p> <p>10 MR. SLATER: Just so you know, lunch</p> <p>11 is here.</p> <p>12 MS. JONES: Okay.</p> <p>13 BY MS. JONES:</p> <p>14 Q Is it your judgment that she would benefit</p> <p>15 from participation in a pain management program?</p> <p>16 A I don't know.</p> <p>17 MS. JONES: Let's stop and have</p> <p>18 lunch.</p> <p>19 (Luncheon recess taken from 1:13 p.m.</p> <p>20 to 2:34 p.m.)</p> <p>21 (Exhibit No. 1220 was marked for</p> <p>22 identification.)</p> <p>23 BY MS. JONES:</p> <p>24 Q We have marked as Exhibit 1220 the list of</p> <p>25 materials reviewed. Doctor, have you reviewed this?</p> | <p style="text-align: right;">Page 324</p> <p>1 your counsel has just provided, you have been paid a</p> <p>2 total of \$328,647 as of October 15, 2012; correct?</p> <p>3 A I have no reason to doubt the document. I</p> <p>4 do not know the number off the top of my head.</p> <p>5 MR. SLATER: I can represent to you</p> <p>6 this was the accurate number as of the date of</p> <p>7 disclosure. There have been subsequent invoices;</p> <p>8 it's just not updated.</p> <p>9 BY MS. JONES:</p> <p>10 Q Have there been subsequent invoices since</p> <p>11 October 15?</p> <p>12 A Yes.</p> <p>13 Q How frequently do you invoice plaintiffs'</p> <p>14 counsel?</p> <p>15 A Once a month.</p> <p>16 Q What was the date of the last invoice?</p> <p>17 A November 1st.</p> <p>18 Q Do you know for what amount that was?</p> <p>19 A I don't.</p> <p>20 MS. JONES: Counsel, can you tell me?</p> <p>21 MR. SLATER: I can find out. I don't</p> <p>22 know off the top of my head, but I'll find out the</p> <p>23 amount.</p> <p>24 BY MS. JONES:</p> <p>25 Q This indicates that your hourly rate</p> |
| <p style="text-align: right;">Page 323</p> <p>1 A Have I reviewed that document?</p> <p>2 Q Yes, ma'am.</p> <p>3 A Yes.</p> <p>4 Q And I understand that over the lunch hour</p> <p>5 this was changed and the deposition of Dr. --</p> <p>6 MR. SLATER: Antolak.</p> <p>7 BY MS. JONES:</p> <p>8 Q -- Antolak was added to this?</p> <p>9 A Correct.</p> <p>10 Q And also a video of some explanation was</p> <p>11 added to this?</p> <p>12 A Yes.</p> <p>13 Q Is there anything else that you have</p> <p>14 reviewed that's not on this document?</p> <p>15 A No.</p> <p>16 Q Did you actually review the deposition of</p> <p>17 Dr. Antolak over the lunch hour?</p> <p>18 A I skimmed it, yes. I skimmed it.</p> <p>19 Q Did you skim or review any other materials</p> <p>20 over the lunch hour?</p> <p>21 A The most recent follow-up on Mrs. Gross</p> <p>22 after having had her first Botox injection.</p> <p>23 Q Anything else?</p> <p>24 A No.</p> <p>25 Q According to the financial disclosure that</p> | <p style="text-align: right;">Page 325</p> <p>1 became \$350 an hour in July of 2012; is that</p> <p>2 correct?</p> <p>3 A Again, I don't have any reason to doubt</p> <p>4 that. I don't recollect that myself.</p> <p>5 Q You recollect and I think you testified</p> <p>6 that you increased your hourly rate from 250 to 350</p> <p>7 dollars an hour, didn't you?</p> <p>8 A Correct.</p> <p>9 Q So that we would have to go back and</p> <p>10 actually get the underlying invoices to see when you</p> <p>11 changed that hourly rate?</p> <p>12 A Well, I believe you just identified that</p> <p>13 as occurring in July 2012.</p> <p>14 Q No. That's what I asked you and you told</p> <p>15 me you didn't know.</p> <p>16 A I do not remember exactly when that</p> <p>17 happened. If you want confirmation beyond what's in</p> <p>18 front of you, yes, we could go back to the</p> <p>19 individual invoices.</p> <p>20 MR. SLATER: And I'm representing to</p> <p>21 you that is when it happened.</p> <p>22 BY MS. JONES:</p> <p>23 Q Have you changed your hourly rate for</p> <p>24 review of the medical literature as a medical</p> <p>25 writer?</p> |

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| <p style="text-align: right;">Page 326</p> <p>1 A No.</p> <p>2 Q So that remains \$250 an hour?</p> <p>3 A Yes.</p> <p>4 Q What prompted you to change this rate to</p> <p>5 \$350 an hour?</p> <p>6 A I felt with my growing experience and</p> <p>7 expertise over the past almost three years of</p> <p>8 reviewing the documents and so on that that added</p> <p>9 experience increased the value of my time.</p> <p>10 Q At any time, Doctor, have you totaled the</p> <p>11 amount of the invoices to confirm that what you've</p> <p>12 been paid is \$328,000-plus?</p> <p>13 A No.</p> <p>14 Q Since October 15 approximately how much</p> <p>15 time have you spent in this litigation?</p> <p>16 A Not including the time since I arrived in</p> <p>17 New Jersey?</p> <p>18 Q Well, let's divide it up. Before you</p> <p>19 arrived in New Jersey.</p> <p>20 A I would say between 30 and 40 hours.</p> <p>21 Q Since October 15th?</p> <p>22 A I don't like to guess.</p> <p>23 Q My recollection is that you testified</p> <p>24 yesterday that you had spent approximately 30 hours</p> <p>25 a week the last several months preparing for this</p> | <p style="text-align: right;">Page 328</p> <p>1 Q So that would have been roughly ten and a</p> <p>2 half hours?</p> <p>3 A Yes.</p> <p>4 Q And today did you work any before you came</p> <p>5 here for the deposition?</p> <p>6 A Yes. I worked this morning for about an</p> <p>7 hour.</p> <p>8 Q And how do you charge for your travel?</p> <p>9 A We haven't discussed that yet.</p> <p>10 Q You expect your expenses to be reimbursed,</p> <p>11 I assume?</p> <p>12 A Yes.</p> <p>13 Q And you expect to be compensated for your</p> <p>14 time and travel?</p> <p>15 A Yes.</p> <p>16 Q Before we took a lunch break, we were</p> <p>17 talking about whether or not Ms. Gross would benefit</p> <p>18 from a pain management program. Do you remember</p> <p>19 that?</p> <p>20 A Yes.</p> <p>21 Q Have you seen or do you know of the</p> <p>22 success of programs such as the Mayo Pain Clinic</p> <p>23 program in treating pelvic pain?</p> <p>24 A I do not know.</p> <p>25 Q Do you believe that Ms. Gross would</p> |
| <p style="text-align: right;">Page 327</p> <p>1 deposition and the reports and so forth.</p> <p>2 A Well, I'm still guessing, but a better</p> <p>3 guess would probably be between 50 and 60 hours.</p> <p>4 Q And when did you arrive in New Jersey?</p> <p>5 That's before you came to New Jersey?</p> <p>6 A Correct.</p> <p>7 Q When did you come to New Jersey?</p> <p>8 A Saturday about noontime.</p> <p>9 Q And since that time, since the time that</p> <p>10 you arrived in New Jersey, how many hours have you</p> <p>11 spent?</p> <p>12 A On Saturday Adam and I worked until about</p> <p>13 6:30. And then I went to the hotel and worked for</p> <p>14 perhaps two hours. On Sunday --</p> <p>15 Q So that would have been a total of how</p> <p>16 many hours? Eight hours?</p> <p>17 A Approximately. On Sunday Adam and I</p> <p>18 worked together for about eight hours and then in</p> <p>19 the evening I worked for about three hours, so that</p> <p>20 would be 11 hours.</p> <p>21 Q And then yesterday you had how much time?</p> <p>22 A Yesterday I worked in the morning for</p> <p>23 about two hours. And then we had the deposition.</p> <p>24 And then I worked in the evening for about half an</p> <p>25 hour.</p> | <p style="text-align: right;">Page 329</p> <p>1 benefit from pain management?</p> <p>2 A Are you referring specifically to this</p> <p>3 program now or pain management in general?</p> <p>4 Q In general.</p> <p>5 A I believe she may benefit. She would</p> <p>6 hopefully benefit.</p> <p>7 Q You would agree that one's perception of</p> <p>8 pain can be influenced by one's psychological</p> <p>9 well-being?</p> <p>10 A Yes.</p> <p>11 Q If you were treating Mrs. Gross today</p> <p>12 based upon what you know, what treatment, if any,</p> <p>13 would you prescribe for her?</p> <p>14 A As under what realm? As a</p> <p>15 urogynecologist?</p> <p>16 Q If Ms. Gross walked into your office today</p> <p>17 with what you understand to be her current medical</p> <p>18 condition, is there any treatment that you would</p> <p>19 prescribe to her?</p> <p>20 A Well, of course, I would take her history,</p> <p>21 which is already very familiar to me, but I would</p> <p>22 make sure I understood that from her standpoint,</p> <p>23 especially in terms of her current symptoms. I</p> <p>24 would perform an examination. I would determine</p> <p>25 what aspects of her condition I may able to address,</p> |

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| <p style="text-align: right;">Page 330</p> <p>1 what additional consultations would be beneficial in 2 her overall management. And I would go from there. 3 Q As you sit here today, do you have any 4 opinion as to what other consultations would be 5 beneficial to her in her overall management? 6 A She has a pain management specialist. She 7 has her family practitioner. She sees 8 urogynecologists. She's receiving psychological 9 counseling. She sees a urologist. She undergoes 10 physical therapy. I can't think of any other 11 consultations that I could offer her at this time. 12 Q Is there any medical treatment that you as 13 a urogynecologist would offer her today? 14 A Well, to the extent possible, considering 15 her conditions are now more likely than not 16 permanent, I think she's receiving the -- unless 17 something new happens, her current management I 18 think is addressing all of her issues and offering 19 her what there is available, although limited, 20 because she's not in a state where cure is a 21 possibility for her, she's in a state of palliation. 22 Q What is your prognosis or what is your 23 opinion as to her prognosis if you have one? 24 A Specific to any one of her conditions or 25 all of them?</p> | <p style="text-align: right;">Page 332</p> <p>1 Q Is there anything other than the 2 ultrasounds upon which you rely for your opinion 3 that there are some residual pieces of mesh? 4 A To my understanding of the operative 5 reports, specific areas, such as the placement of 6 the two superficial anterior arms through the 7 obturator space and the two deep anterior arms 8 through the obturator space and the two posterior 9 arms through the ischiorectal fossa, have not been 10 specifically sought with the idea of removing them. 11 In fact, Mrs. Gross has been informed that 12 it would be -- it would introduce additional 13 morbidity. And her husband, Mr. Gross, had a very 14 insightful observation: If it's too difficult to 15 remove the mesh that was implanted, how is -- or too 16 dangerous, how is it not too dangerous to implant it 17 in the first place? 18 MS. JONES: Move to strike as 19 nonresponsive. 20 BY MS. JONES: 21 Q Are you relying upon his deposition or 22 have you spoken with Mr. Gross? 23 A I have not spoken with Mr. Gross. 24 Q Have you reviewed the reports of the 25 defense experts with respect to Ms. Gross?</p> |
| <p style="text-align: right;">Page 331</p> <p>1 Q To any condition about which you've been 2 asked to opine. 3 A I believe that her condition, while it may 4 wax and wane within a certain restricted range over 5 time, is otherwise permanent. 6 Q And when you say her condition is 7 permanent, will you describe for me what condition 8 it is that you believe is permanent? 9 A I believe her pain is permanent. It's 10 possible she may experience some relief, not likely 11 resolution of the pelvic muscle spasm component of 12 her pain. I believe her urinary retention is 13 permanent and she will require intermittent 14 self-catheterization for the rest of her life. To 15 the extent that she has mesh remaining, she remains 16 at lifelong risk for mesh-related complications like 17 mesh erosion. 18 Q Do you have any evidence that she, in 19 fact, has mesh remaining in her body? 20 A To my knowledge, there are at least pieces 21 of the six mesh arms that were implanted in Linda. 22 Q And have you done anything in any way to 23 quantify the amount of mesh, if any, that's left? 24 A No, that's not possible. Ultrasound can 25 visualize mesh -- can visualize mesh.</p> | <p style="text-align: right;">Page 333</p> <p>1 A Yes. 2 Q Which reports have you reviewed? 3 A Kavalier, Minkin. I believe those are the 4 two that are specific to Mrs. Gross. 5 Q Do you have any opinions or disagreements 6 with either of those reports? 7 A Yes, I do. 8 Q Can you tell me what they are? 9 A Can I have the report, please? 10 Q If you have it with you. 11 MR. SLATER: Well, I can go have 12 somebody print copies. You don't have them? 13 MS. JONES: I'm asking for the 14 disagreements with the report. 15 MR. SLATER: I understand. She's 16 saying she needs to be able -- they're lengthy 17 reports. What she's going to likely do now is go 18 page by page for probably an hour or two. I'm not 19 being facetious. I can go get them printed, but if 20 the question's going to be to list all her 21 disagreements -- 22 BY MS. JONES: 23 Q Have you, in fact, prepared a report 24 listing all your disagreements? 25 A I have made comments.</p> |

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| <p style="text-align: right;">Page 334</p> <p>1 Q Where did you make comments?</p> <p>2 A In a document.</p> <p>3 Q In what document?</p> <p>4 A I don't remember the title. It's not a</p> <p>5 report as in those reports of mine.</p> <p>6 Q It's not a report that's been furnished to</p> <p>7 us?</p> <p>8 A Correct.</p> <p>9 Q Let me ask you, Doctor, to summarize if</p> <p>10 you can your disagreements with those of</p> <p>11 Dr. Kavalier.</p> <p>12 A I really prefer to have the report in</p> <p>13 front of me.</p> <p>14 MR. SLATER: I'm going to go get</p> <p>15 someone to print it.</p> <p>16 THE WITNESS: Because my criticisms</p> <p>17 are very specific and I'll do a much better job when</p> <p>18 I have the report in front of me.</p> <p>19 BY MS. JONES:</p> <p>20 Q So as we sit here today, you really don't</p> <p>21 remember what those criticisms are?</p> <p>22 MR. SLATER: That's unfair. I</p> <p>23 object. You asked her to list her criticisms. And</p> <p>24 any competent and reasonable witness and attorney</p> <p>25 would want to have the document in front of them in</p> | <p style="text-align: right;">Page 336</p> <p>1 you're going to ask someone about a document, give</p> <p>2 it to them and say, here, I'm going to ask you some</p> <p>3 questions about the document.</p> <p>4 So we'll take a break. I'm going to</p> <p>5 go get those two reports. And, counsel, you have</p> <p>6 the materials reviewed. You know that she saw all</p> <p>7 the expert reports. It's all listed. I'll go get</p> <p>8 those two reports because that's your particular</p> <p>9 question. It's actually three reports. Take a</p> <p>10 break while I get them.</p> <p>11 (Short recess.)</p> <p>12 MR. SLATER: So I have given her the</p> <p>13 reports now.</p> <p>14 BY MS. JONES:</p> <p>15 Q Okay. I have a question before you go</p> <p>16 through the reports, Doctor. You said that you had</p> <p>17 prepared a document critiquing these reports for</p> <p>18 Mr. Slater?</p> <p>19 A Yes.</p> <p>20 Q Did you review that report in preparation</p> <p>21 for this deposition?</p> <p>22 MR. SLATER: Objection to the form.</p> <p>23 You can answer.</p> <p>24 THE WITNESS: Considering the defense</p> <p>25 expert reports were only served on October 15th, it</p> |
| <p style="text-align: right;">Page 335</p> <p>1 order to answer the question when Kavalier's report</p> <p>2 is nearly 50 pages long, Minkin wrote two lengthy</p> <p>3 reports. So she has the right to have the document</p> <p>4 in front of her if you're going to ask her any</p> <p>5 questions about the document; right? So I'm going</p> <p>6 to get them.</p> <p>7 MS. JONES: I'm asking her questions</p> <p>8 about her opinions, counsel.</p> <p>9 MR. SLATER: You're asking what?</p> <p>10 MS. JONES: I'm asking her questions</p> <p>11 about her opinions. I asked her to summarize those</p> <p>12 opinions. I think I'm entitled to an answer to</p> <p>13 that.</p> <p>14 MR. SLATER: You're going to get an</p> <p>15 answer. You object to me putting the reports in</p> <p>16 front of the witness?</p> <p>17 MS. JONES: I don't have any</p> <p>18 objection to it.</p> <p>19 MR. SLATER: So I'll go get them.</p> <p>20 MS. JONES: But I think that's the</p> <p>21 reason we ask you to bring documents with you.</p> <p>22 MR. SLATER: Hang on. Hang on. With</p> <p>23 all due respect, you're taking a deposition, you're</p> <p>24 asking questions of the witness about documents you</p> <p>25 didn't bring. The customary thing that we do is if</p> | <p style="text-align: right;">Page 337</p> <p>1 has been in the past couple of weeks. I don't know</p> <p>2 that I reviewed it specifically in preparation for</p> <p>3 my own deposition.</p> <p>4 BY MS. JONES:</p> <p>5 Q Have you reviewed that document since you</p> <p>6 arrived here on Saturday?</p> <p>7 A No.</p> <p>8 Q When did you actually prepare it?</p> <p>9 A I don't know. Sometime after</p> <p>10 October 15th.</p> <p>11 Q Sometime in the last two to three weeks</p> <p>12 anyway?</p> <p>13 A Correct.</p> <p>14 Q Now, what I would like you to do is to</p> <p>15 summarize for me your criticisms or disagreements,</p> <p>16 however you choose to characterize it, with</p> <p>17 Dr. Kavalier.</p> <p>18 A A general summary of my opinions is that</p> <p>19 she does not address all the issues of substance,</p> <p>20 she makes misleading and inaccurate statements, and</p> <p>21 her opinion -- I disagree with the opinion -- her</p> <p>22 opinions as to the causation of Mrs. Gross'</p> <p>23 injuries.</p> <p>24 Q Do you know Dr. Kavalier?</p> <p>25 A No.</p> |

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| <p style="text-align: right;">Page 338</p> <p>1 Q Ever met her?</p> <p>2 A No.</p> <p>3 Q Know anything about her practice beyond</p> <p>4 what you know in the report?</p> <p>5 A I think I Googled her once her report was</p> <p>6 provided to me.</p> <p>7 Q Ever read any of her publications?</p> <p>8 A No.</p> <p>9 Q When you said that she did not address all</p> <p>10 of the material aspects of the case, what areas do</p> <p>11 you believe she failed to address?</p> <p>12 A She failed to address, among many other</p> <p>13 things, Ethicon's failure to warn physicians and</p> <p>14 patients of the material risks, many of which</p> <p>15 affected Linda Gross directly, like the risk of</p> <p>16 urinary retention.</p> <p>17 In fact, Dr. Robinson right before he</p> <p>18 joined Ethicon was so alarmed about the extent and</p> <p>19 severity of urinary retention that he was seeing in</p> <p>20 his patients and in other -- the patients of other</p> <p>21 physicians with whom he was in contact when he first</p> <p>22 arrived at Ethicon, he felt strongly that he wanted</p> <p>23 to include a specific warning in the Prolift® IFU</p> <p>24 about the risk of this prolonged and severe urinary</p> <p>25 retention.</p> | <p style="text-align: right;">Page 340</p> <p>1 exposure -- mesh erosion and recurrent mesh erosion</p> <p>2 that could not be resolved, vaginal anatomic</p> <p>3 distortion and scarring that could not be addressed</p> <p>4 in a way that a woman was able to engage in normal</p> <p>5 sexual relations, to name a few.</p> <p>6 Shall I keep going?</p> <p>7 Q Anything else that you believe that she</p> <p>8 failed to address that she should have addressed in</p> <p>9 this context.</p> <p>10 A She failed to address Ethicon's failure to</p> <p>11 warn that patients on anticoagulation therapy are</p> <p>12 contraindicated to undergo the Prolift® procedure.</p> <p>13 This was another warning that Ethicon had placed in</p> <p>14 its instructions for use, for example, for the TVT®,</p> <p>15 which is only two trocar passes, and yet in the</p> <p>16 Prolift® procedure with six trocar passes through</p> <p>17 the deep pelvis a warning was not added. It was</p> <p>18 considered. And Ethicon, for reasons that are</p> <p>19 inexplicable to me, never made that change.</p> <p>20 There was a warning that Axel Arnaud</p> <p>21 wanted to include in the Prolift® IFU right before</p> <p>22 Prolift® was getting ready to launch about pelvic</p> <p>23 pain and pain with intercourse. And this warning</p> <p>24 was not added to the IFU because the IFUs had</p> <p>25 already been printed and the change -- Ethicon</p> |
| <p style="text-align: right;">Page 339</p> <p>1 This was discussed. Opinions from</p> <p>2 experienced Prolift® users were taken -- were</p> <p>3 obtained urgently at a meeting. They didn't know</p> <p>4 what caused this. Ethicon didn't study it. They</p> <p>5 drafted something to be put into the IFU and it</p> <p>6 never made it into the IFU. So physicians and</p> <p>7 patients went unwarned of this severe risk after the</p> <p>8 Prolift® procedure.</p> <p>9 MS. JONES: Move to strike as</p> <p>10 nonresponsive.</p> <p>11 BY MS. JONES:</p> <p>12 Q Doctor, other than the risk of urinary</p> <p>13 retention that you believe that Dr. Kavalier failed</p> <p>14 to address, are there other issues that you believe</p> <p>15 she failed to address?</p> <p>16 MR. SLATER: Objection to the form of</p> <p>17 the question.</p> <p>18 You can answer.</p> <p>19 THE WITNESS: She failed to address</p> <p>20 Ethicon's failure to warn of the risk of</p> <p>21 complications after the Prolift® procedure that were</p> <p>22 untreatable.</p> <p>23 BY MS. JONES:</p> <p>24 Q Such as?</p> <p>25 A Such as chronic pelvic pain, mesh</p> | <p style="text-align: right;">Page 341</p> <p>1 didn't want to make the change and reprint the IFUs.</p> <p>2 MS. JONES: Move to strike as</p> <p>3 nonresponsive.</p> <p>4 BY MS. JONES:</p> <p>5 Q What other areas do you believe -- and I'm</p> <p>6 just asking you to list them -- that Dr. Kavalier</p> <p>7 failed to address?</p> <p>8 MR. SLATER: And just for the record,</p> <p>9 you want her to just go off the top of her head and</p> <p>10 list generally? She has the report here.</p> <p>11 MS. JONES: She's got the report in</p> <p>12 front of her. I'm just asking her --</p> <p>13 MR. SLATER: You can keep listing off</p> <p>14 the top of your head and then eventually you can sit</p> <p>15 down and go through the report if you want to if</p> <p>16 counsel wants the complete list.</p> <p>17 THE WITNESS: One more thing is that</p> <p>18 Dr. Kavalier failed to address the failure of Ethicon</p> <p>19 to properly study Prolift® before launch in a way</p> <p>20 that would allow for appropriate patient selection,</p> <p>21 and that includes patients with preexisting pain</p> <p>22 conditions, when it was learned only later that</p> <p>23 these patients would have an -- or were at higher</p> <p>24 risk to have an exacerbation of their preexisting</p> <p>25 pain condition or the development of a new pain</p> |

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| <p style="text-align: right;">Page 342</p> <p>1 condition such that implantation of the Prolift® was</p> <p>2 contraindicated in them, that they could develop</p> <p>3 complications that were untreatable, that left them</p> <p>4 with devastating, life-altering complications for</p> <p>5 which there is no treatment.</p> <p>6 Dr. Kavalier failed to address the</p> <p>7 fact that Ethicon failed to study the complications</p> <p>8 that were known and foreseeable that would occur</p> <p>9 with the Prolift® procedure. And they failed to</p> <p>10 include this in their internal design processes</p> <p>11 which, if they had performed properly, the Prolift®</p> <p>12 would have never reached the market.</p> <p>13 MS. JONES: Move to strike as</p> <p>14 nonresponsive.</p> <p>15 BY MS. JONES:</p> <p>16 Q Do you know, Doctor, whether or not</p> <p>17 Dr. Kavalier actually used the Prolift®?</p> <p>18 A I believe she stated so in her report.</p> <p>19 Q She actually had experience using Prolift®</p> <p>20 with her patients, did she not?</p> <p>21 A Evidently. I just answered that. I'd</p> <p>22 like to continue to address your previous question.</p> <p>23 Q Other things that you say she left out?</p> <p>24 A The other disagreements I have with her</p> <p>25 opinions.</p> | <p style="text-align: right;">Page 344</p> <p>1 A Yes.</p> <p>2 Q What are they?</p> <p>3 A On Page 27, No. 3, Dr. Kavalier claims that</p> <p>4 Mrs. Gross has recurrent prolapse. She did not have</p> <p>5 recurrent prolapse. Her opinion is that Prolift®</p> <p>6 was an appropriate choice to treat her bothersome</p> <p>7 recurrent prolapse. And, again, she does not have</p> <p>8 recurrent prolapse.</p> <p>9 Prolift® is a safe and effective treatment</p> <p>10 of pelvic organ prolapse. I do not agree with that.</p> <p>11 Q Let me make myself clear. Maybe my</p> <p>12 question wasn't clear. The opinion that you have</p> <p>13 about Prolift® is set forth in your report, is it</p> <p>14 not?</p> <p>15 A Correct.</p> <p>16 Q My question is: Are there any opinions</p> <p>17 that you have in response to Dr. Kavalier that are</p> <p>18 not set forth in your report?</p> <p>19 A Yes.</p> <p>20 Q That's what I'm trying to identify is just</p> <p>21 that discrete group of opinions that you have not</p> <p>22 previously written about.</p> <p>23 A Okay.</p> <p>24 MR. SLATER: Just objection to the</p> <p>25 form.</p> |
| <p style="text-align: right;">Page 343</p> <p>1 Q Let me separate these if I can, because I</p> <p>2 thought that we were talking about first and I</p> <p>3 thought my question was first what is it that you</p> <p>4 believe that she left out and didn't address,</p> <p>5 because that was where you started first.</p> <p>6 A Well, what you asked me first was what I</p> <p>7 did I disagree with in her report. And on Page --</p> <p>8 give me just a second.</p> <p>9 Okay. So on Page 69 she is addressing</p> <p>10 the -- she is addressing -- she's making a</p> <p>11 counterpoint to my opinion in which she states:</p> <p>12 Ethicon adequately warns about the risk of nerve</p> <p>13 damage in its Prolift® IFU and patient brochure.</p> <p>14 And in other places in her report she</p> <p>15 opines that Ethicon's Prolift® IFU adequately warned</p> <p>16 of the risks. So what I was doing was providing you</p> <p>17 with my opinion in contrast to that that Ethicon did</p> <p>18 not adequately warn of the risks in its Prolift®</p> <p>19 IFU.</p> <p>20 So now shall I continue with my</p> <p>21 disagreements with her opinions?</p> <p>22 Q I would like to hear all of your</p> <p>23 disagreements. Before we spend time doing that, let</p> <p>24 me ask you this: Are there any disagreements with</p> <p>25 her opinions that are not set forth in your report?</p> | <p style="text-align: right;">Page 345</p> <p>1 You can answer.</p> <p>2 THE WITNESS: Page 27, No. 5: Linda</p> <p>3 Gross chose to undergo so many surgeries after the</p> <p>4 original implant that it is impossible to attribute</p> <p>5 her present condition to Prolift®. Many of these</p> <p>6 surgeries were against the advice of her</p> <p>7 physician -- physicians.</p> <p>8 This is absolutely unreasonable.</p> <p>9 Mrs. Gross went through the process of multiple</p> <p>10 surgeries at each time sitting down with her</p> <p>11 surgeon, discussing her condition, and making a</p> <p>12 joint decision to go ahead with surgery. She didn't</p> <p>13 set out to have the number of surgeries she had.</p> <p>14 She had the number of surgeries she had as a direct</p> <p>15 result of the Prolift® procedure and the permanent</p> <p>16 Prolift® mesh implantation. At each time she was</p> <p>17 faced with the decision as to whether she would</p> <p>18 undergo surgery again. This was in consultation</p> <p>19 with her surgeon and under his or her recommendation</p> <p>20 to go forward because that was a reasonable choice</p> <p>21 at the time. To suggest --</p> <p>22 BY MS. JONES:</p> <p>23 Q May I just ask -- let me just ask one</p> <p>24 question.</p> <p>25 MR. SLATER: Don't interrupt her. I</p> |

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| <p style="text-align: right;">Page 346</p> <p>1 mean, she's in the middle of her answer. 2 MS. JONES: I just want to ask this 3 question. 4 BY MS. JONES: 5 Q Is there documentation in the medical 6 records that surgeons advised her against having 7 further surgery? 8 A Yes. I would like to expand on that and 9 also complete the answer to the question. 10 Q I'm perfectly happy for you to complete 11 your answer. 12 A It is unreasonable and unethical to 13 suggest that Mrs. Gross underwent surgery at any 14 particular instance because no surgeon acting 15 ethically would perform a surgery that he or she did 16 not feel that the possible benefit of that surgery 17 outweighed the possible risks. It would be 18 unethical to do otherwise. To suggest that 19 Mrs. Gross underwent surgery against the advice of 20 her physicians ignores that obvious and very basic, 21 fundamental aspect of the practice of surgery. 22 Q Are you finished? 23 A That's the rest of my answer to that 24 question. Shall I continue with the remaining 25 disagreements that I have with Dr. Kavalier that are</p> | <p style="text-align: right;">Page 348</p> <p>1 pudendal -- the pudendal nerve was the surgery that 2 she had with Dr. Hibner, the neurolysis and the 3 combination of procedures that accompanied that. 4 It's ludicrous to suggest that pudendal neuralgia 5 was the result of that surgery when pudendal 6 neuralgia was the indication for that surgery. At 7 no other time did Mrs. Gross undergo a surgery that 8 directly addressed the pudendal nerve or that would 9 place the pudendal nerve at risk for the kind of 10 outcome she had, the pudendal neuralgia, except for 11 the indexed Prolift® procedure and the result of the 12 Prolift® mesh implantation. 13 No. 8: Linda Gross' incomplete 14 bladder emptying cannot be attributed to Prolift®. 15 I disagree with that opinion and the basis for that 16 is explained in my report. 17 No. 9: Linda Gross' two mesh 18 extrusions are the result of post-implant surgeries, 19 not her July 2006 implant surgery. I disagree with 20 this opinion. And, again, it is ludicrous to 21 suggest that mesh erosion as a complication can 22 occur unless you have mesh implantation. She had 23 Prolift® mesh implantation, and as a result of that 24 mesh implantation she subsequently developed the 25 complication of mesh erosion.</p> |
| <p style="text-align: right;">Page 347</p> <p>1 not otherwise in my report? 2 Q I thought that that was what you had just 3 told me you had completed. 4 A That was No. 5. I was just completing my 5 response to No. 5 on Page 27. 6 Q Please tell me what else you disagree with 7 that's not otherwise in your report. 8 MR. SLATER: Objection to the form. 9 You can answer. 10 THE WITNESS: No. 6: Linda Gross' 11 current condition is attributable to pelvic muscle 12 spasms. Dr. Kavalier ignores the reality that Linda 13 Gross has pelvic muscle spasm in addition to other 14 conditions. She acts like pelvic muscle spasm is 15 the exclusive cause of the constellation of Linda 16 Gross' symptoms and I do not agree with that. 17 Prolift® did not -- this is No. 7: 18 Prolift® did not cause pudendal neuralgia in Linda 19 Gross. If Ms. Gross at some time -- excuse me -- at 20 some point developed a pudendal injury, it cannot be 21 attributed to Prolift®, particularly in light of her 22 preexisting history of pelvic floor defect and her 23 extensive history of post-implant surgeries. 24 The only surgery that Mrs. Gross 25 underwent that specifically addressed her</p> | <p style="text-align: right;">Page 349</p> <p>1 No. 10, Page 28: The known risks of 2 Prolift® are adequately warned about in the 3 product's IFU and patient brochure. I utterly 4 disagree with this. In -- I'm going to try to 5 confine my remarks to what is not already in my 6 report at your request. Linda Gross read the 7 patient -- the Prolift® patient brochure and she 8 relied on it in making her decision to go ahead with 9 the Prolift®. She believed the false and misleading 10 statements in the Prolift® patient brochure. 11 MS. JONES: Move to strike as 12 nonresponsive. 13 MR. SLATER: She's in the middle of 14 her answer. 15 MS. JONES: I don't care. 16 BY MS. JONES: 17 Q I mean, I've asked only for an 18 identification of what it is that you disagree with 19 in the report that's not otherwise set forth in your 20 report. And if you disagree with the statement that 21 they failed to warn, that's all I need. 22 MR. SLATER: You realize my concern 23 with the question is it's a very difficult thing to 24 say what's in the report, what's not in the report. 25 You know, we're being cautious because we're</p> |

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| <p style="text-align: right;">Page 350</p> <p>1 concerned about someone later saying something fell 2 within the crack. 3 BY MS. JONES: 4 Q Let's answer this question, Doctor: Have 5 you set forth in your roughly 600 pages of report 6 your opinions with respect to the warnings and the 7 contents of the IFU? 8 A Yes. 9 Q Have you set forth in your report your 10 opinions with respect to the warnings and content of 11 the patient brochure? 12 A Yes. I would like to point out you asked 13 me specifically with regard to Linda Gross and with 14 regard to what's not already in my report. I'm 15 telling you about the patient brochure and what 16 Linda relied on. That's not in my report. 17 Q Let me ask you this: You're relying upon 18 Ms. Gross' deposition testimony? 19 A Correct. 20 So am I allowed to go forward? 21 MR. SLATER: Just hang on. She'll 22 ask a new question. 23 THE WITNESS: I thought I was still 24 answering the last question. I thought I was still 25 answering the question where you asked me --</p> | <p style="text-align: right;">Page 352</p> <p>1 deposition today, I am going to withdraw my question 2 to ask you to go through and outline the various 3 disagreements with Dr. Kavalier. 4 Let me ask you this question: Have you 5 reviewed the report of Dr. Minkin? 6 A Yes. 7 Q Have you reviewed the report of 8 Dr. Stevens? 9 A Yes. 10 Q In the document that you prepared with 11 your comments about these reports for Mr. Slater, 12 did you include in there comments about Dr. Minkin 13 and Dr. Stevens? 14 A I don't recall making comments about 15 Dr. Stevens' report. 16 Q In your report and opinions we talked 17 about, you have said that you believe that Ms. Gross 18 experienced fear, anxiety, and depression on a 19 permanent basis; is that correct? 20 A Yes. 21 Q Can you tell me what that is based upon? 22 A What my opinion is based upon? 23 Q Exactly. 24 A Yes. 25 Q What's the basis for that opinion?</p> |
| <p style="text-align: right;">Page 351</p> <p>1 BY MS. JONES: 2 Q Is it your intent, Doctor, to walk through 3 every page and every paragraph that Dr. Kavalier 4 wrote in her report and say you disagree with it? 5 MR. SLATER: Before you answer, I 6 have to place an objection. Just one second. 7 Counsel, if you ask the question what 8 does she disagree with in Dr. Kavalier's report, I 9 assume you'd want her to go through and tell you 10 everything, so that's what you would expect her to 11 do. It's a bit argumentative and pejorative to kind 12 of say it as if that's something that you wouldn't 13 expect her to do. 14 BY MS. JONES: 15 Q Do you disagree with every paragraph in 16 Dr. Kavalier's report? 17 A I can't make that claim until I, again, go 18 through every paragraph in Dr. Kavalier's report. I 19 was trying to be responsive to your question and you 20 interrupted me. 21 MS. JONES: Let me take 30 seconds. 22 (Short recess.) 23 BY MS. JONES: 24 Q Doctor, in the interest of time and 25 because I would really like to finish this</p> | <p style="text-align: right;">Page 353</p> <p>1 A The basis for that opinion is my review of 2 her medical records and the depositions of her 3 treating physicians. 4 Q Have you reviewed any medical records 5 relating to any psychological issues that she 6 experienced before having Prolift®? 7 MR. SLATER: Objection to the form of 8 the question. 9 You can answer. 10 THE WITNESS: Could you repeat the 11 question, please? 12 BY MS. JONES: 13 Q Have you reviewed any records relating to 14 Mrs. Gross' psychological condition prior to the 15 Prolift® surgery? 16 A Yes. 17 Q What? 18 A Well, for example, when she had her 19 surgery in 2001, the hysterectomy and Burch 20 procedure, she experienced headaches that were 21 spinal headaches, and she had a prolonged course 22 with that that was very distressing to her. 23 Q Anything else? 24 A Not that I can recall right now. 25 Q Let me turn to Ms. Wicker for a second.</p> |

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| <p style="text-align: right;">Page 354</p> <p>1 Can you tell me, Doctor, if Ms. Wicker had presented 2 to you in 2008 when she saw Dr. Bercik, what 3 treatment, if any, you would have recommended for 4 her? 5 A As we discussed before, I would counsel 6 her regarding behavioral and lifestyle changes, 7 pelvic muscle exercises, pessary use, or surgery. 8 Considering her duration of symptoms was relatively 9 short, I would want to get a better sense from her 10 as to the severity and the impact of her symptoms on 11 her life as we discussed the different treatment 12 options. 13 After that discussion, if she felt that 14 she would like to proceed with surgery, I would 15 discuss with her the options, with or without a 16 hysterectomy, of apical suspensions such as the 17 uterosacral ligament suspension and the anterior 18 colporrhaphy for her anterior vaginal prolapse. 19 Q And do you feel that those surgical 20 procedures would have been appropriate for her 21 condition based upon your review of the medical 22 records? 23 A Yes. 24 Q Would you have recommended surgery to her 25 for her condition?</p> | <p style="text-align: right;">Page 356</p> <p>1 Q What do you know about him? 2 A I know he is the head of urogynecology at 3 Yale. I can't remember anything else specific. 4 Q You've already told us that you spoke with 5 Dr. Elliott about whether or not Ms. Wicker suffered 6 from interstitial cystitis I believe? 7 A I certainly spoke with Dr. Elliott. I 8 don't remember specifically exactly what we 9 discussed about Mrs. Wicker. 10 Q Did Ms. Wicker suffer from interstitial 11 cystitis in your judgment? 12 MR. SLATER: Objection to the form of 13 the question. 14 THE WITNESS: That is in her medical 15 history so I would accept her historical report of 16 that, yes. 17 BY MS. JONES: 18 Q Have you attempted to evaluate whether or 19 not there was any other source of pelvic pain for 20 Ms. Wicker other than what you attribute to Prolift® 21 or the Prolift® surgery? 22 A Well, at this point Mrs. Wicker also has 23 an element of pelvic muscle spasm which is likely 24 related to her pain, which is due to the Prolift® 25 procedure. Other than that, I don't know that she</p> |
| <p style="text-align: right;">Page 355</p> <p>1 A Well, again, I would want to get a better 2 sense from her -- as I'm sure you can understand, 3 what gets recorded in the medical record is a 4 shorthand for what actually goes on in the 5 counseling session. So what's not present in the 6 medical record are -- is a high level of detail 7 regarding her symptomatic state, the duration of her 8 symptoms, their intensity, her degree of bother 9 related to her symptoms, her impact on her quality 10 of life, and so on. So before I could say with 11 certainty that I would recommend surgery for her, I 12 would need that additional information. 13 Q Do I understand then that based upon your 14 review of the medical records you can't say one way 15 or another whether or not the surgery was 16 appropriate for her? 17 MR. SLATER: Objection. 18 You can answer. 19 THE WITNESS: Dr. Bercik is an 20 experienced respected surgeon. I am not going to 21 disagree with his decision after he counseled 22 Mrs. Wicker to recommend surgery to her. 23 BY MS. JONES: 24 Q Do you know Dr. Bercik? 25 A No.</p> | <p style="text-align: right;">Page 357</p> <p>1 has any other diagnoses in her pelvis that would 2 account for her symptoms. 3 Q Pelvic muscle spasms can certainly occur 4 in the absence of the presence of mesh, can't they? 5 A Yes. 6 Q Did you review Mrs. Wicker's medical 7 records for other physical conditions that could 8 account for or contribute to her source of pelvic 9 pain or her pelvic pain? 10 A Yes, I reviewed her records. 11 Q Did you identify in reviewing the records 12 any other physical conditions that would account for 13 or contribute to her pelvic pain? 14 A No, I did not. 15 Q Based upon your review of the medical 16 records, was there anything in the medical records 17 that should have served as a contraindication to the 18 surgery, the Prolift® surgery, in Ms. Wicker? 19 A Now there is an understanding that 20 patients with preexisting pain conditions like 21 migraine headaches and interstitial cystitis are 22 contraindicated to undergoing the Prolift® procedure 23 because they have a higher risk of exacerbation of 24 their current condition or the development of a new 25 condition. That information, although known and</p> |

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| <p style="text-align: right;">Page 358</p> <p>1 foreseeable by Ethicon, had not been distributed or 2 communicated by Ethicon to physicians and patients. 3 Q Other than Ms. Wicker's interstitial 4 cystitis, what conditions did you see in the medical 5 records that suggested that Ms. Wicker suffered from 6 any type of chronic pain syndrome? 7 A Migraine headaches. 8 Q Anything else? 9 A Arthritis. 10 Q And where was the arthritis? 11 A In her hips. 12 Q Anything else? 13 A No. 14 Q Was there anything about what you learned 15 from the medical records or the depositions in the 16 case about Ms. Wicker's activities that would have 17 contributed to her chronic pain? 18 A No. 19 Q What is your prognosis as we sit here 20 today for Ms. Wicker? 21 A She carries a lifelong risk of further 22 mesh erosions and requirement -- and the required 23 treatment. She has recurrent prolapse that may or 24 may not be correctable, treatable. She may not be 25 able to undergo surgery for that because of</p> | <p style="text-align: right;">Page 360</p> <p>1 reported that he had restored the length of the 2 vagina to I want to say 10 centimeters? Does that 3 sound right? 4 A Yes. 5 Q And that Dr. Raz thought he had a good 6 result with that? 7 A He had a good result in terms of, as I 8 said, the creation of an anatomic vaginal canal. He 9 was unable to obviously turn back time and give her 10 normal vaginal tissue, vaginal tissue in the absence 11 of fibrosis and scarring and mesh fragments that 12 will continue to pose a risk of recurrent mesh 13 erosion and the need for further surgery and 14 functional aspects of her sexual function in terms 15 of pain, vaginal pain, pelvic pain, pelvic muscle 16 spasm that unfortunately he is also unable to 17 reverse. 18 Q And upon what do you rely that she has 19 residual mesh? 20 A The ultrasound identification of mesh and 21 the fact that she continues to present with 22 recurrent mesh erosion. 23 Q And when was she last treated for mesh 24 erosion of which you're aware? 25 A In October she had granulation tissue,</p> |
| <p style="text-align: right;">Page 359</p> <p>1 complications from the Prolift®. She has pelvic 2 pain and vaginal pain that more than likely than not 3 is a permanent condition. This affects her ability 4 to have normal sexual relations with her husband in 5 that she has an anatomic vaginal canal, but the 6 dysfunction of the vaginal tissues and the pelvic 7 muscles and the scarring and the fibrosis prevent 8 her from having a normal enjoyable sexual life with 9 her husband. 10 Q Let me follow up with some questions on 11 that. First, what surgery, if any, would you 12 recommend be considered for Ms. Wicker to correct 13 her prolapse? 14 A That is a very difficult question to 15 answer that Dr. Raz is currently struggling with. 16 She has lost so much of her normal vaginal tissue 17 because of the scarring and the recurrent mesh 18 erosion and the recurrent -- repeated surgeries. 19 I've certainly never faced a situation like that in 20 my clinical experience, so her surgical options in 21 terms of treating her cystocele would have to be 22 very creative. 23 (Discussion off the record.) 24 BY MS. JONES: 25 Q Am I correct, Doctor, that Dr. Raz</p> | <p style="text-align: right;">Page 361</p> <p>1 which in the presence of mesh is often a precursor 2 to the exposure. The last time -- 3 Q October of this year? 4 A Yes. And that was treated in the office. 5 Q Was any mesh specifically noted at that 6 time? 7 A She did not have an overt mesh erosion. 8 Q Who saw the granulation tissue? 9 A Dr. Raz. 10 Q And how was she treated for the 11 granulation tissue at that time? 12 A She was treated with a topical cautery 13 agent, silver nitrate. 14 Q And do you know how she responded to that? 15 A I do not. 16 Q Do you know whether or not Ms. Wicker is 17 on any pain medication at this time? 18 A I do not know that off the top of my head. 19 Q Do you know or have an opinion as to 20 whether Ms. Wicker would benefit from a pain 21 management course? 22 A I don't know. She may; she may not. 23 Q If she were your patient, would you 24 recommend that she receive treatment for pain 25 management?</p> |

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| <p style="text-align: right;">Page 362</p> <p>1 A And by that -- what do you mean 2 specifically by "pain management"? She is having 3 pain management. 4 Q Based upon what you know of Ms. Wicker's 5 current condition, if she came to see you and you 6 examined her, what would you recommend for her, if 7 anything, in terms of pain management? 8 A You mean different or in addition to what 9 she is currently receiving? 10 Q Or the same as what she's currently 11 receiving. 12 A Well, she's having physical therapy. She 13 is treated with a muscle relaxant for her pelvic 14 muscle spasm. She is using vaginal estrogen cream 15 to -- in an attempt to help the vaginal tissue. 16 She's waiting to see if her vaginal tissue -- she's 17 waiting to see if enough time can elapse without 18 another mesh erosion for the consideration of 19 treatment of her cystocele. I don't think I have 20 anything to add to that. 21 Q Other than the interstitial cystitis and 22 the migraine headaches, is there anything 23 significant in Ms. Wicker's preexisting medical 24 history that's important to you in terms of your 25 opinions?</p> | <p style="text-align: right;">Page 364</p> <p>1 A Correct. 2 Is this a good time for a break? 3 MS. JONES: We can. I'm trying to 4 finish. But if you want to take a break, we will. 5 THE WITNESS: Yes. 6 (Short recess.) 7 BY MS. JONES: 8 Q Doctor, have you seen any of the pathology 9 on Ms. Wicker? 10 A Yes. 11 Q What did you see? 12 A Photomicrographs of resected tissue and 13 mesh. And I have seen photographs of resected 14 tissue and mesh. 15 Q And from whom did those photomicrographs 16 come? 17 A From Dr. Welch. 18 Q And from whom did you obtain copies of the 19 photographs? 20 A From Dr. Raz. 21 Q You reviewed the records relating to Dr. 22 Raz' surgery on Ms. Wicker? 23 A Correct. 24 Q Had you ever seen anyone perform a surgery 25 using the materials that Dr. Raz used in the</p> |
| <p style="text-align: right;">Page 363</p> <p>1 A I consider arthritis as another chronic 2 pain condition that she has. 3 Q Anything else? 4 A No. 5 Q Do you know what the cause or do you have 6 an opinion of what the cause of Ms. Wicker's 7 prolapse was? 8 A Well, as I think we discussed previously, 9 the etiology of prolapse is not fully understood. 10 She has some of the epidemiologic risk factors that 11 have been identified, such as vaginal births. Other 12 than those factors, I don't see anything in her 13 history that stands out in particular. 14 Q Do you have an opinion as to what the 15 cause of Ms. Wicker's interstitial cystitis was? 16 A Even less so is the etiology of 17 interstitial cystitis understood. And as I 18 mentioned before, it's really just a constellation 19 of symptoms. So, no, I do not have an understanding 20 of what the cause of Mrs. Wicker's interstitial 21 cystitis is. 22 Q And I think you told us that rather than 23 treating a patient with interstitial cystitis, you 24 would have referred them to a urologist for 25 recommendations for treatment?</p> | <p style="text-align: right;">Page 365</p> <p>1 surgery? 2 A In -- you're referring to any of his 3 surgeries? 4 Q Well, you know that he -- these are my 5 words, not his words, but did a construct using 6 polypropylene? Are you aware of that? 7 A The Prolene® suture -- 8 Q Yes. 9 A -- is that what you're referring to? Yes. 10 Q You know that Prolene® suture is 11 polypropylene? 12 A Correct. 13 Q Had you ever seen anyone use that before? 14 A No. 15 Q That's not something that you saw or used 16 or trained on when you were practicing? 17 A Correct. 18 Q Do you have an opinion as to what the 19 risks, if any, were or are with that procedure using 20 that material? 21 A Above and beyond or different from the 22 risks that we've already talked about in terms of 23 surgery? 24 Q Associated with the use of that Prolene® 25 suture as he did.</p> |

39 (Pages 362 to 365)

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| <p style="text-align: right;">Page 366</p> <p>1 A It would be possible to have a suture 2 erosion or an uncovering of the suture by -- through 3 or under the vaginal epithelium. That's the only 4 additional risk that I can think of, you know, 5 besides all the other things we've talked about. 6 Q How would you have counseled your patient 7 on the use of that material in a way different from 8 the use of mesh? 9 A If a suture erosion occurred, I would 10 counsel the patient that that is a simple problem to 11 solve in that the suture can be simply snipped out. 12 It doesn't involve a dissection. It doesn't involve 13 the likelihood of recurrent mesh erosion. And in 14 general it would be just a much simpler procedure 15 than resecting mesh. 16 Q As I understand it, Dr. Raz' surgery 17 involved a series of interlocking sutures; is that 18 your understanding? 19 A Yes. 20 Q Have you ever seen any published article 21 on that procedure anywhere using interlocking 22 sutures? 23 A Not that I can recall. I haven't 24 specifically looked for it. 25 Q You're not aware of any randomized</p> | <p style="text-align: right;">Page 368</p> <p>1 patients and his understanding of the risks and 2 benefits. In that case I would not consider it 3 experimental. 4 In the other scenario, I learn about 5 this procedure in some way and I decide I'm going to 6 try it on my patient. In that case it would be 7 experimental and I would counsel her in that way. 8 BY MS. JONES: 9 Q Do you know whether or not Dr. Raz had 10 performed this same procedure previously? 11 A I do not know. 12 Q Have you seen any of the radiology in this 13 case? 14 A In Dr. Raz' deposition, images of the 15 ultrasound and MRI were used as exhibits. 16 Q But have you seen those? 17 A Yes. His deposition was videotaped so, 18 yes, I have seen those. 19 Q I mean did you just see it on the screen 20 on the videotape or do you have digitalized versions 21 of those materials? 22 A The former. 23 Q So you actually watched the video and saw 24 those displayed on the screen? 25 A Correct.</p> |
| <p style="text-align: right;">Page 367</p> <p>1 controlled clinical trial using that procedure and 2 those materials? 3 A No. 4 Q If you had been counseling a patient, 5 would you have suggested to the patient that that 6 would be an experimental therapy? 7 A Well, as we've already established, I have 8 not been trained in using this procedure. It would 9 depend on what the collective experience had been 10 with that procedure. 11 Q Well, I guess my question, Doctor, is 12 knowing what you know today about that procedure and 13 the absence of information about that procedure in 14 the medical literature, would you have counseled or 15 told your patients that it was an experimental 16 procedure? 17 MR. SLATER: Objection to the form of 18 the question; foundation also. 19 You can answer. 20 THE WITNESS: I'll create two 21 scenarios for you. One scenario, let's pretend I'm 22 a fellow with Dr. Raz and I spend three years 23 training with him and I gain from his experience and 24 skill in teaching and his experience in the 25 performance of this particular procedure with his</p> | <p style="text-align: right;">Page 369</p> <p>1 Q You've not looked at them otherwise where 2 you were actually holding them in your hand? 3 A Correct. 4 Q You state in your report that you believe 5 that Ms. Wicker has permanent impairment. Can you 6 tell me what the basis of that opinion is? 7 A Yes. First I'd like to mention something 8 that I forgot which is relevant to your question, 9 and that is her urinary tract symptoms, which is 10 frequency, urgency, and bladder pain. I believe 11 those symptoms are permanent subject to the 12 management that she's currently receiving. 13 Q Let me ask you that. Did she suffer those 14 symptoms before she had her Prolift® surgery? 15 A To my understanding, her symptoms related 16 to her history of interstitial cystitis were stable, 17 so she did not have current symptoms related to her 18 history of interstitial cystitis before her Prolift® 19 surgery. 20 Q Had she had the same symptoms in the 21 past -- 22 A I don't believe she -- 23 Q -- associated with interstitial cystitis? 24 A Excuse me. I don't believe she had 25 bladder pain. I believe she had frequency/urgency</p> |

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| <p style="text-align: right;">Page 370</p> <p>1 that led to her historical diagnosis of interstitial 2 cystitis.</p> <p>3 Q Now, I think you were answering the 4 question of permanent impairment.</p> <p>5 A Yes. So her other conditions, her vaginal 6 pain and dyspareunia, I believe those are permanent 7 conditions. Her pelvic muscle spasm contributing to 8 her pelvic pain is undergoing treatment with 9 physical therapy and muscle relaxants. It's 10 possible she may experience some improvement in 11 those symptoms. I am not hopeful that she will 12 experience true resolution.</p> <p>13 Q When you're talking about she may 14 experience some improvement in those symptoms, would 15 that be improvement in the symptoms of pelvic spasms 16 and dyspareunia?</p> <p>17 A Correct, and vaginal pain.</p> <p>18 Q And vaginal pain.</p> <p>19 A She has symptoms related to her cystocele. 20 And as I mentioned before, she's waiting -- she and 21 Dr. Raz are waiting to see if a sufficient amount of 22 time will elapse for him to be confident or 23 relatively confident that mesh erosion will not 24 recur and that he may be able to proceed with the 25 cystocele repair. If he judges that he cannot, then</p> | <p style="text-align: right;">Page 372</p> <p>1 permanent.</p> <p>2 Q Can I just ask one question? I asked you 3 first about permanent impairment and then I asked 4 you secondly about disability.</p> <p>5 A Yes.</p> <p>6 Q And I'm trying to discern whether or not 7 those are one and the same or they're two different 8 issues. Let me just say if I'm reading this, I look 9 at disability as saying disability in the sense of 10 being unable to participate, for example, in gainful 11 employment or the normal activities to which she has 12 been engaged in. Is that what you're --</p> <p>13 A Well --</p> <p>14 Q Is that how you would define it, first?</p> <p>15 MR. SLATER: Objection.</p> <p>16 You can answer.</p> <p>17 THE WITNESS: I would take a broader 18 view of disability affecting every minute of every 19 hour of every day of her life. And that includes, 20 as I said, being disabled in her ability to enjoy 21 normal sexual relations with her husband, being 22 disabled in terms of limitations on her activities 23 based on her frequency, urgency, and bladder pain 24 and the necessary proximity of a restroom and her 25 pelvic pain in general and, as I said, the</p> |
| <p style="text-align: right;">Page 371</p> <p>1 her cystocele will be a permanent condition. She 2 continues to be at risk for recurrent mesh erosion 3 and the risks associated with her treatment, which 4 would be surgical.</p> <p>5 Q I'm sorry. You said the risk associated 6 with her treatment would be?</p> <p>7 A Surgical.</p> <p>8 Q Would be the risk associated with surgery, 9 is that what --</p> <p>10 A That's what I intended to mean.</p> <p>11 Q I'm sorry. I just didn't understand.</p> <p>12 You say in your report that Ms. Wicker is 13 disabled. Can you tell me the basis of your opinion 14 that she is disabled?</p> <p>15 A She is disabled to the extent that she 16 can't enjoy a normal sexual life with her husband. 17 She is disabled to the extent that she is troubled 18 by chronic pain and all of the consequences that 19 attend that. She is disabled to the extent related 20 to her urinary symptoms with frequency and urgency 21 and bladder pain that induce anxiety and worry that 22 she will have an incontinent episode in public, for 23 example, and face the humiliation of that if she 24 can't reach a restroom in time. And those 25 conditions, her urinary symptoms, I believe are</p> | <p style="text-align: right;">Page 373</p> <p>1 consequences that attend chronic pain and the 2 disability that inflicts on her quality of life.</p> <p>3 BY MS. JONES:</p> <p>4 Q If you were her doctor, based upon what 5 you understand her current condition to be, would 6 you restrict her activities in any way?</p> <p>7 A In my opinion, the harm has been done. 8 The harm was done when she had the Prolift® 9 procedure and the permanent Prolift® mesh 10 implantation. I don't believe she can further harm 11 herself by engaging in the activities that provide 12 her with a semblance of the quality of life that she 13 had before.</p> <p>14 Q So the answer is that you would not 15 restrict her activities in any way today?</p> <p>16 A I would restrict her activities to her 17 tolerance of her symptoms.</p> <p>18 Q Can you switch back to Ms. Gross for a 19 second?</p> <p>20 A I can.</p> <p>21 Q Would you put any restrictions or 22 limitations on Ms. Gross and her activities if you 23 saw her today?</p> <p>24 A Again, the harm has been done with the 25 Prolift® procedure and the permanent Prolift® mesh</p> |

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| <p style="text-align: right;">Page 374</p> <p>1 implantation. I don't believe she can further harm 2 herself with her activities. And, again, if -- the 3 restrictions would be only to the -- her tolerance 4 of her symptoms such that she doesn't precipitate a 5 level of pain that's intolerable to her. 6 MS. JONES: Did someone join us on 7 the phone? 8 MR. SLATER: I think that was the 9 sound of someone hanging up actually. 10 MS. JONES: I think it was, too. 11 That's what I was checking. 12 MR. CAMERON: This is Roger. I think 13 it was just a line check. 14 MS. JONES: Dr. Weber, I thank you. 15 I think that's all I have right now. 16 MR. SLATER: I have a couple brief 17 follow-up questions. I'll only be three or four 18 hours. 19 BY MR. SLATER: 20 Q A few moments ago in the context of Pam 21 Wicker you were asked about the symptoms of her 22 cystocele, her bladder prolapse that she currently 23 has. Remember that? 24 A Yes. 25 Q And within the constellation of symptoms</p> | <p style="text-align: right;">Page 376</p> <p>1 Q Do you have an understanding of the fact 2 that due to her condition, Linda Gross is unable to 3 conduct her normal daily activities and to work; 4 correct? 5 A Yes. 6 Q And that's a result of her condition? 7 A Yes. 8 Q It also affects her ability to engage in 9 her day-to-day activities that she would prefer to 10 engage in? 11 A Yes. 12 Q You were asked earlier about Dr. Minkin's 13 report about Linda Gross. In her report Dr. Minkin 14 talked about the episode in 2001 where Linda Gross 15 suffered from spinal headaches and it took about a 16 year for those to resolve. You saw that? 17 A Yes. 18 Q And you saw where Dr. Minkin actually 19 referred to those as migraines? Did you see that? 20 A Yes. 21 Q In the context of what you've testified to 22 earlier with regard to chronic pain as a 23 contraindication and in the context of Dr. Benson's 24 overall testimony, how does that fit in if, in fact, 25 one were to consider that to be a chronic pain or</p> |
| <p style="text-align: right;">Page 375</p> <p>1 or the results of her cystocele, is one of those 2 results obstructed voiding? 3 A Yes. 4 Q And that was discussed by Dr. Raz as well 5 during his testimony; correct? 6 A Yes. 7 Q And what is the obstructed voiding and why 8 is that due to this recurrent prolapse that has 9 occurred since all these surgeries had to be done 10 after the Prolift®? 11 A What happens with a cystocele, when the 12 bladder drops down, there's a kinking effect between 13 the urethra and the bladder so that it becomes very 14 difficult for the bladder to empty normally. And, 15 in fact, Mrs. Wicker is in the very uncomfortable 16 position of having to stand in order to be able to 17 empty her bladder to try to overcome this obstructed 18 voiding. 19 Q Do you believe as long as the cystocele is 20 not able to be repaired that that will continue? 21 A Yes. 22 Q You were asked a question a moment ago 23 about Linda Gross and whether her activities would 24 be restricted by you. Remember that question? 25 A Yes.</p> | <p style="text-align: right;">Page 377</p> <p>1 migraine condition? How would that impact on your 2 overall opinion? 3 A Yes. Well, as we discussed previously, 4 what has been learned by surgeons over time is that 5 patients with a preexisting pain condition are at 6 much higher risk for either the exacerbation of 7 their existing pain condition or the development of 8 a new pain condition after the Prolift® procedure 9 such that it is considered -- the Prolift® procedure 10 is considered now contraindicated in those patients. 11 So given the fact that Mrs. Gross has this history, 12 then that would have served as a contraindication 13 for her to undergo the Prolift® procedure at all. 14 Q With regard to a comparison of risks 15 between certain native tissue repairs with sutures 16 and the Prolift®, you were asked about various 17 risks. Remember that mostly yesterday and a little 18 today? 19 A Yes. 20 Q Is there a significant difference between 21 the severity, the duration, and the treatability of 22 pain with intercourse or discomfort with intercourse 23 that a woman might experience after a native tissue 24 repair as compared to the dyspareunia that a woman 25 could suffer following a Prolift®?</p> |

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| <p style="text-align: right;">Page 378</p> <p>1 A Yes. There --</p> <p>2 Q I don't need you to explain. I just want</p> <p>3 to establish that.</p> <p>4 A Okay.</p> <p>5 Q Counsel obviously can ask you about it,</p> <p>6 but I just want to make sure it's clear. I know</p> <p>7 it's explained in your report.</p> <p>8 Earlier in the deposition you testified</p> <p>9 with regard to what you termed as Ethicon's</p> <p>10 deception to surgeons at the time that Linda Gross</p> <p>11 and Pam Wicker had the procedure. Remember that</p> <p>12 testimony?</p> <p>13 A Yes.</p> <p>14 Q And in the course of your reports, did you</p> <p>15 detail your evaluation of the different things that</p> <p>16 you would term Ethicon's deception of surgeons</p> <p>17 beginning with the launch up through those</p> <p>18 surgeries?</p> <p>19 A Yes.</p> <p>20 Q One thing that you talked about was the</p> <p>21 failure of Ethicon to obtain 510(k) clearance. Are</p> <p>22 there other aspects to Ethicon's deception beyond</p> <p>23 their failure to tell doctors that the product had</p> <p>24 not been cleared by the FDA?</p> <p>25 A Yes.</p> | <p style="text-align: right;">Page 380</p> <p>1 that context; correct?</p> <p>2 A Yes.</p> <p>3 Q You were asked about the summary of</p> <p>4 medical records that was provided to you by my</p> <p>5 office and I think you said one or more deposition</p> <p>6 summaries. Ultimately, beyond just using those as a</p> <p>7 short summary of what had been provided just to get</p> <p>8 an idea of what was there, did you ultimately read</p> <p>9 each of the records yourself and read each of the</p> <p>10 depositions yourself and rely on your own reading of</p> <p>11 the source materials to form your opinions?</p> <p>12 A Yes.</p> <p>13 MR. SLATER: I have no other</p> <p>14 questions.</p> <p>15 BY MS. JONES:</p> <p>16 Q Let me follow up just briefly, Doctor.</p> <p>17 You were asked about dyspareunia following the use</p> <p>18 of transvaginal mesh. Have you actually treated a</p> <p>19 woman who has had transvaginal mesh implanted for</p> <p>20 prolapse for dyspareunia?</p> <p>21 A No.</p> <p>22 Q You were asked about the obstructed</p> <p>23 voiding that you say Ms. Wicker is experiencing?</p> <p>24 A Yes.</p> <p>25 Q Is that something that could be treated</p> |
| <p style="text-align: right;">Page 379</p> <p>1 Q You talked earlier in the deposition about</p> <p>2 your reliance on certain physicians with regard to</p> <p>3 the fact that the Prolift® mesh can harbor a chronic</p> <p>4 low-grade infection which can cause recurrent</p> <p>5 erosions and other harm to a woman. Remember that</p> <p>6 testimony?</p> <p>7 A Yes.</p> <p>8 Q And you said that two of the physicians</p> <p>9 you relied on were Dr. Raz and you referred to the</p> <p>10 doctor from Connecticut. That would be</p> <p>11 Dr. Kreutzer?</p> <p>12 A Yes.</p> <p>13 Q Did you also rely on the opinions and</p> <p>14 experience of Dr. Margolis as well in that regard?</p> <p>15 A Yes.</p> <p>16 Q You were asked if you had spoken with any</p> <p>17 Prolift® users about the Prolift® or the Prolift®</p> <p>18 professional education. Do you remember that?</p> <p>19 A Yes.</p> <p>20 Q You did, in fact, have the ability and you</p> <p>21 did actually read the depositions of Dr. Benson,</p> <p>22 Dr. Bercik, Dr. Raders, Dr. Hinoul, Dr. Robinson,</p> <p>23 Dr. Kirkemo, Dr. Jafri from the Firman case, you had</p> <p>24 the opportunity to read extensive deposition</p> <p>25 testimony from multiple users of the Prolift® in</p> | <p style="text-align: right;">Page 381</p> <p>1 with the use of a Burch procedure?</p> <p>2 MR. SLATER: You're asking</p> <p>3 specifically in Pam Wicker as things stand now?</p> <p>4 THE WITNESS: The Burch</p> <p>5 colposuspension is indicated for the treatment of</p> <p>6 stress incontinence. It is not indicated to resolve</p> <p>7 obstructed voiding.</p> <p>8 BY MS. JONES:</p> <p>9 Q Do you know whether or not the use of that</p> <p>10 procedure could be used for obstructed voiding in</p> <p>11 Ms. Wicker?</p> <p>12 A Well, of course, it could be. I wouldn't</p> <p>13 recommend it.</p> <p>14 Q Do you know whether or not the TVT®</p> <p>15 procedure is available for use in obstructed</p> <p>16 voiding?</p> <p>17 A No.</p> <p>18 MS. JONES: That's all I have.</p> <p>19 BY MR. SLATER:</p> <p>20 Q Just to follow up on those last two</p> <p>21 questions, when you said Burch could be used, were</p> <p>22 you saying that you would recommend it or think it's</p> <p>23 an appropriate treatment for Pam Wicker?</p> <p>24 A No. I was just responding in the general</p> <p>25 sense that anybody can do anything, but I would not</p> |

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| <p>1 recommend it.</p> <p>2 Q The problems that Dr. Raz testified with</p> <p>3 regard to during his trial testimony, those would</p> <p>4 apply to any effort to treat the cystocele at this</p> <p>5 point; correct?</p> <p>6 A Yes.</p> <p>7 MR. SLATER: No other questions.</p> <p>8 (Witness excused.)</p> <p>9 (Whereupon the deposition adjourned</p> <p>10 at 4:47 p.m.)</p> <p>11 - - -</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p> | <p>1 INSTRUCTIONS TO WITNESS</p> <p>2</p> <p>3 Please read your deposition over carefully</p> <p>4 and make any necessary corrections. You should</p> <p>5 state the reason in the appropriate space on the</p> <p>6 errata sheet for any corrections that are made.</p> <p>7 After doing so, please sign the errata</p> <p>8 sheet and date it.</p> <p>9 You are signing same subject to the</p> <p>10 changes you have noted on the errata sheet, which</p> <p>11 will be attached to your deposition.</p> <p>12 It is imperative that you return the</p> <p>13 original errata sheet to the deposing attorney</p> <p>14 within thirty (30) days of receipt of the deposition</p> <p>15 transcript by you. If you fail to do so, the</p> <p>16 deposition transcript may be deemed to be accurate</p> <p>17 and may be used in court.</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <p>1 CERTIFICATE</p> <p>2</p> <p>3 I, KIMBERLY A. OVERWISE, a Certified</p> <p>4 Court Reporter and Notary Public of the State of New</p> <p>5 Jersey, do hereby certify that prior to the</p> <p>6 commencement of the examination, ANNE M. WEBER,</p> <p>7 M.D., M.S., was duly sworn by me to testify to the</p> <p>8 truth, the whole truth and nothing but the truth.</p> <p>9</p> <p>10 I DO FURTHER CERTIFY that the</p> <p>11 foregoing is a verbatim transcript of the testimony</p> <p>12 as taken stenographically by and before me at the</p> <p>13 time, place and on the date hereinbefore set forth,</p> <p>14 to the best of my ability.</p> <p>15</p> <p>16 I DO FURTHER CERTIFY that I am</p> <p>17 neither a relative nor employee nor attorney nor</p> <p>18 counsel of any of the parties to this action, and</p> <p>19 that I am neither a relative nor employee of such</p> <p>20 attorney or counsel, and that I am not financially</p> <p>21 interested in this action.</p> <p>22</p> <p>23 KIMBERLY A. OVERWISE</p> <p>24 CCR: 30X100224600</p> <p>25 Dated: November 19, 2012</p> | <p>1 E R R A T A S H E E T</p> <p>2 - - - - -</p> <p>3</p> <table border="1"> <thead> <tr> <th data-bbox="813 1171 873 1203">PAGE</th> <th data-bbox="959 1171 1036 1203">LINE</th> <th data-bbox="1057 1171 1166 1203">CHANGE</th> </tr> </thead> <tbody> <tr><td>4</td><td></td><td></td></tr> <tr><td>5</td><td></td><td></td></tr> <tr><td>6</td><td>REASON:</td><td></td></tr> <tr><td>7</td><td></td><td></td></tr> <tr><td>8</td><td>REASON:</td><td></td></tr> <tr><td>9</td><td></td><td></td></tr> <tr><td>10</td><td>REASON:</td><td></td></tr> <tr><td>11</td><td></td><td></td></tr> <tr><td>12</td><td>REASON:</td><td></td></tr> <tr><td>13</td><td></td><td></td></tr> <tr><td>14</td><td>REASON:</td><td></td></tr> <tr><td>15</td><td></td><td></td></tr> <tr><td>16</td><td>REASON:</td><td></td></tr> <tr><td>17</td><td></td><td></td></tr> <tr><td>18</td><td>REASON:</td><td></td></tr> <tr><td>19</td><td></td><td></td></tr> <tr><td>20</td><td>REASON:</td><td></td></tr> <tr><td>21</td><td></td><td></td></tr> <tr><td>22</td><td>REASON:</td><td></td></tr> <tr><td>23</td><td></td><td></td></tr> <tr><td>24</td><td>REASON:</td><td></td></tr> <tr><td>25</td><td></td><td></td></tr> </tbody> </table> | PAGE | LINE | CHANGE | 4 | | | 5 | | | 6 | REASON: | | 7 | | | 8 | REASON: | | 9 | | | 10 | REASON: | | 11 | | | 12 | REASON: | | 13 | | | 14 | REASON: | | 15 | | | 16 | REASON: | | 17 | | | 18 | REASON: | | 19 | | | 20 | REASON: | | 21 | | | 22 | REASON: | | 23 | | | 24 | REASON: | | 25 | | |
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| 6 | REASON: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 8 | REASON: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 12 | REASON: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 14 | REASON: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 16 | REASON: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 18 | REASON: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 20 | REASON: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 22 | REASON: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 24 | REASON: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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Confidential - Subject to Stipulation and Order of Confidentiality

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ACKNOWLEDGMENT OF DEPONENT

I, ANNE M. WEBER, M.D., M.S., do
 hereby certify that I have read the foregoing pages,
 213-385, and that the same is a correct
 transcription of the answers given by me to the
 questions therein propounded, except for the
 corrections or changes in form or substance, if any,
 noted in the attached Errata Sheet.

 ANNE M. WEBER, M.D., M.S. DATE

Subscribed and sworn
 to before me this
 ____ day of _____, 2012.

My commission expires: _____

 Notary Public

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LAWYER'S NOTES

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